UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN,	**CIVIL ACTION NUMBER:**
and IRBESARTAN PRODUCTS	**1:19-md-02875-RMB-SAK**
LIABILITY LITIGATION	**Rule 702 Hearing**

Mitchell H. Cohen Building & U.S. Courthouse
4th and Cooper Streets
Camden, New Jersey 08101
Tuesday, September 17, 2024
Commencing at 1:18 p.m.

B E F O R E: **THE HONORABLE RENÉE MARIE BUMB,**
CHIEF UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

HONIK LLC
BY: RUBEN HONIK, ESQUIRE
DAVID J. STANOCH, ESQUIRE
1515 Market Street, Suite 1100
Philadelphia, Pennsylvania 19102
Co-Lead Counsel for MDL Plaintiffs

MAZIE SLATER KATZ & FREEMAN, LLC
BY: ADAM M. SLATER, ESQUIRE
CHRISTOPHER J. GEDDIS, ESQUIRE
103 Eisenhower Parkway, Suite 207
Roseland, New Jersey 07068
Co-Lead Counsel for MDL Plaintiffs

MARTIN, HARDING & MAZZOTTI, LLP
BY: ROSEMARIE RIDDELL BOGDAN, ESQUIRE
1 Wall Street
Albany, New York 12205
Counsel for Plaintiffs' Steering Committee

John J. Kurz, Official Court Reporter
John_Kurz@njd.uscourts.gov
(856)576-7094

Proceedings recorded by mechanical stenography; transcript produced by computer-aided transcription.

A P P E A R A N C E S: (Continued)

NIGH GOLDENBERG RASO & VAUGHN, PLLC
BY: C. BRETT VAUGHN, ESQUIRE
DANIEL A. NIGH, ESQUIRE
14 Ridge Square NW, Third Floor
Washington, D.C. 20016
Co-Lead Class Counsel for Third-Party Payor Economic Loss

PRETI FLAHERTY BELIVEAU & PACHIOS, CHARTERED LLP
BY: ELIZABETH FLETCHER QUINBY, ESQUIRE
One City Center, PO Box 9546
Portland, Maine 04112
Co-Lead Class Counsel for Third-Party Payor Economic Loss

SLACK & DAVIS LLP
BY: JOHN RANDOLPH DAVIS, ESQUIRE
6001 Bold Ruler Way, Suite 100
Austin, TX 78746
Counsel for Plaintiffs

SKADDEN, ARPS, SLATE, MEAGHER & FLOM, LLP
BY: JESSICA DAVIDSON, ESQUIRE
ALLISON M. BROWN, ESQUIRE
One Manhattan West, Suites 42-128
New York, New York 10001
Counsel for Defendants Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Prinston Pharmaceutical, Inc., and Solco Healthcare U.S., LLC (collectively ZHP)

SKADDEN, ARPS, SLATE, MEAGHER & FLOM, LLP
BY: NINA R. ROSE, ESQUIRE
1440 New York Avenue, N.W.
Washington, D.C. 20005
Counsel for Defendants Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Prinston Pharmaceutical, Inc., and Solco Healthcare U.S., LLC (collectively ZHP)

KIRKLAND & ELLIS LLP
BY: DEVORA W. ALLON, P.C.
ALEXIA R. BRANCATO, ESQUIRE
601 Lexington Avenue
New York, New York 10022
Counsel for Defendants Torrent Pharma, Inc. and Torrent Pharmaceuticals Ltd. (collectively Torrent)

(Appearances continued onto next page)

A P P E A R A N C E S: (Continued)

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI LLP
BY: CLEM C. TRISCHLER, ESQUIRE
JASON M. REEFER, ESQUIRE
One Oxford Centre, 38th Floor
Pittsburgh, Pennsylvania 15219
Counsel for Defendant Mylan Pharmaceuticals, Inc.

GREENBERG TRAURIG LLP
BY: VICTORIA DAVIS LOCKARD, ESQUIRE
3333 Piedmont Road, NE, Suite 2500
Atlanta, Georgia 30305
Counsel For Defendants Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Actavis LLC, Actavis Pharma, Inc. (collectively Teva)

GREENBERG TRAURIG LLP
BY: GREGORY E. OSTFELD, ESQUIRE
TIFFANY M. ANDRAS, ESQUIRE
77 West Wacker Drive, Suite 3100
Chicago, Illinois 60601
Counsel For Defendants Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Actavis LLC, Actavis Pharma, Inc. (collectively Teva)

WALSH PIZZI O'REILLY FALANGA LLP
BY: LIZA M. WALSH, ESQUIRE
Three Gateway Center, 100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
Counsel for Defendant Teva

ARCHER & GREINER, P.C.
BY: MAUREEN THERESA COGHLAN, ESQUIRE
1025 Laurel Oak Road
Voorhees, NJ 08043
Counsel for the Mylan defendants

CROWELL & MORING LLP
BY: ANDREW KAPLAN, ESQUIRE
1001 Pennsylvania Avenue, NW
Washington, DC 20004
Counsel for Defendant Cardinal Health

BARNES & THORNBURG, LLP
BY: KARA KAPKE, ESQUIRE
11 South Meridian Street
Indianapolis, IN 46204
Counsel for Retailer Defendants and CVS Pharmacy, Inc., and Walmart, Walgreens

A P P E A R A N C E S: (Continued)

FALKENBERG IVES LLP
BY: KIRSTIN B. IVES, ESQUIRE
230 W Monroe Street, Suite 2220
Chicago, Illinois 60606
Counsel for Defendant Humana

NORTON ROSE FULBRIGHT US LLP
BY: D'LESLI DAVIS, ESQUIRE
2200 Ross Avenue
Suite 3600
Dallas, Texas 75201
Counsel for Defendant Mckesson Corp.

Also present:

Arthur Roney, The Courtroom Deputy

Loretta Smith, Esquire, Judicial Law Clerk to the Honorable Robert B. Kugler (Ret.)

INDEX

(PROCEEDINGS held in open court before the Honorable Renée Marie Bumb, Chief United States District Judge, at 1:18 p.m. as follows:)

THE COURTROOM DEPUTY: All rise.

THE COURT: All right. Good afternoon.

Have a seat. Thank you. Okay. We'll start with appearances, please.

MR. SLATER: Hello, Your Honor. Adam Slater on behalf of the plaintiffs.

MR. DAVIS: John Davis on behalf of the plaintiffs.

MR. NIGH: Daniel Nigh on behalf of plaintiffs.

MR. STANOCH: David Stanoch for plaintiffs.

THE COURT: Afternoon.

MR. STANOCH: Good afternoon.

MR. OSTFELD: Good afternoon, Your Honor. Greg Ostfeld from Greenberg Traurig on behalf of Teva.

MS. ANDRAS: Afternoon. Tiffany Andras on behalf of Teva.

MS. LOCKARD: Victoria Lockard, Greenberg Traurig, also for Teva.

MS. ALLON: Good afternoon, Your Honor. Devora Allon from Kirkland & Ellis for Torrent.

MS. BRANCATO: Good afternoon. Alexia Brancato, also of Kirkland for Torrent.

MS. BROWN: Good afternoon, Your Honor. Alli Brown

from Skadden for ZHP.

MS. ROSE: Good afternoon, Your Honor. Nina Rose from Skadden for ZHP.

THE COURT: Okay. Good afternoon to all of you.

All right. We'll get started. Your witness.

MR. OSTFELD: Thank you, Your Honor. We call Wayne Gibson.

THE COURT: Okay.

(Witness took the stand.)

THE COURTROOM DEPUTY: Step in the witness stand. Do you swear or affirm?

THE WITNESS: I swear.

THE COURTROOM DEPUTY: Can you place your left hand on the Bible and raise your right hand.

Do you solemnly swear the testimony you're about to give in the case now before this Court will be the truth, the whole truth, and nothing but the truth, so help you God?

THE WITNESS: I do.

WAYNE T. GIBSON, called as a witness for the Defendants, having been first duly sworn by the Deputy, was examined and testified as follows:

THE COURTROOM DEPUTY: Can you please state and spell your full name for the record.

THE WITNESS: Wayne Toussaint Gibson.

THE COURTROOM DEPUTY: Please spell the last name.

THE WITNESS: W-A-Y-N-E, T-O-U-S-S-A-I-N-T, G-I-B-S-O-N.

THE COURTROOM DEPUTY: Thank you.

THE COURT: Thank you. Make yourself comfortable. Please be careful getting into the seat.

THE WITNESS: I will do my best. Thank you.

THE COURT: And if you could bring the microphone closer to you when you speak, okay.

Okay. Counsel.

MR. OSTFELD: Thank you, Your Honor.

Before I begin questioning Mr. Gibson, I just want to say for the record, Mr. Gibson will not be offering at trial opinions on risk corridors or direct and indirect remuneration. Those are two topics that were addressed in plaintiffs' motion. Because he won't be offering those opinions at trial, I'm not planning to address them today unless Your Honor wants to hear about them.

THE COURT: Okay.

DEFENDANT'S EVIDENCE

DIRECT EXAMINATION

BY MR. OSTFELD:

Q. Mr. Gibson, you understand you're here today to give the Court an opportunity to assess your qualifications and the reliability of the opinions you expect to offer at trial?

A. I do, yes.

Q. Have you prepared slides to assist you in presenting your opinions to the Court today?
A. I have, yes.
Q. And do some of those slides contain excerpts of materials that you have considered in connection with the opinions you're offering?
A. They do.
Q. The full versions of those excerpted materials are in a separate binder?
A. That's correct.
MR. OSTFELD: Your Honor, may I approach?
THE COURT: You may.
Thank you.
BY MR. OSTFELD:
Q. Mr. Gibson, what was your assignment in this case?
A. I was asked to review the damages calculations of Professor Conti.
Q. And turning to Slide No. 2 in the presentation, can you begin by providing an overview of the opinions that you expect to offer at trial in this case.
A. Yes. I offered three opinions. The first opinion is that Professor Conti's damages calculations are inflated by her reliance on IQVIA Xponent data which has inflated pricing information.
The second opinion is that Professor Conti fails to

exclude CMS subsidy and payment amounts that class members did not incur.

And the third opinion is that Professor Conti fails to exclude amounts paid by non-class members.

Q. Mr. Gibson, have you reviewed plaintiffs' *Daubert* motion to exclude opinions of Wayne Gibson?

A. I have, yes.

Q. And is it your understanding that motion challenges all three of these opinions?

A. It's my understanding that that motion challenges opinions one and two.

Q. All right. Before we turn to the substance of those two opinions and the plaintiffs' challenges, let's give the Judge a chance to get to know you a little bit better.

Let's move to the next slide, please.

Mr. Gibson, you're being offered in this case as an expert in pharmaceutical claims analysis and the payment processes for prescription drugs?

A. That's correct, yes.

Q. Could you please provide the Court with a brief overview of your educational and professional history.

A. Yes. I have a bachelor's degree in environmental science from College of William and Mary, it's mostly biology and chemistry, and then a master's degree in economics from the University of Delaware.

Q. And your professional background?
A. Yes. I'm currently Senior Managing Director with FTI Consulting based in Washington, DC, and I lead our risk management -- Healthcare Risk Management and Advisory Practice.
Q. Go ahead.
A. So I started my career directly out of graduate school with Arthur Andersen in one of their business consulting units. Following Andersen, going away, in 2002, I followed some partners to Navya Consulting, and then in 2007 joined FTI Consulting in their healthcare practice where I'm focused full time on healthcare.
Q. How long have you been involved in pharmaceutical claims analysis?
A. The first time I began doing any pharmaceutical claims analysis was probably in around 1998.
Q. Okay. What percentage of your work today is litigation versus non-litigation?
A. About 20 percent of my work is disputes in litigation. The rest is risk -- regulatory compliance and operational consulting.
Q. All right. Please provide the Court with a brief overview of the work that you do in your day-to-day work on the non-litigation side as it relates to the opinions you've offered in this case.
A. So, as I mentioned, I provide regulatory compliance and

operational consulting to a variety of entities. So, for example, under the Medicare Advantage Program for Medicare Advantage Part D plans, those are MAPD plans and PDP, that's Part D plans, there are third-party payors. I provide regulatory compliance consulting as it relates to helping them make certain that they're submitting the appropriate data and information to CMS so that CMS can oversee them. If CMS does things like program audits, I will assist them in helping them prepare for those and evaluate the questions that CMS has.

In addition, with, for example, pharmaceutical manufacturers, I've assisted them in pricing and sales and marketing work from a compliance standpoint to help ensure that the information they're submitting to federal programs is appropriate and that their internal controls are appropriate.

With respect to the retail pharmacies, I've assisted them in evaluating their claims adjudication process in helping ensure that they're adjudicating claims appropriately. And then with respect to, for example, PBMs, I've worked with them to ensure that they're, again, compliant with the Part D program guidance and make certain that they're treating beneficiaries and adjudicating claims appropriately.

Q. Your opinions in this case have involved financial modeling, analysis of large datasets, and analysis of CMS guidance; is that correct?

A. That's correct, yes.

Q. And is that the type of work that you perform in your day-to-day non-litigation consulting work?
A. It is, yes.
Q. The methods that you've used in this case to form your opinions, are those the same types of methods you use in your regular non-litigation work?
A. They are, that's correct.
Q. All right. We're going to turn to those methods shortly. Before we do, Professor Conti testified last week on several subjects that I believe the Court is expecting to hear from you on today, so let's start there.

Have you reviewed the transcript of Professor Conti's testimony from last week?
A. I have, yes.
Q. Including her testimony regarding IQVIA Xponent data and her testimony regarding the point of sale and point of payment?
A. I have, yes.
Q. Are these subjects that you also considered and analyzed in forming your own opinions in this case?
A. I did, yes.
Q. So let's begin with Professor Conti's testimony regarding the IQVIA Xponent data which is reflected in part on the next slide.

Well, actually, before we go there, let's start with, would you explain to the Court what IQVIA Xponent data is?

A. Yes.

So IQVIA is a company and Xponent that provides datasets to the industry. Xponent is one of those datasets. The Xponent data is a -- IQVIA takes a sample of pharmacies and asks them questions through surveys and other information about volume and pricing information, and then IQVIA takes that information they get back and then estimates the market based upon that information. IQVIA intends this dataset to support sales, marketing and research applications.

I'd say one other point that I would emphasize is the IQVIA Xponent dataset, in terms of how it's provided and produced, is summary-level information. So it's summarized on a monthly product basis as opposed to a real-world detailed transaction information where you can actually see the individual adjudication in an individual dispensing event.

Q. Okay. Turning now to Professor Conti's testimony regarding IQVIA Xponent and the next slide. Have you reviewed Professor Conti's testimony that IQVIA Xponent is the gold standard?

A. I have, yes.

Q. And then turning to the next slide, have you also reviewed Professor Conti's testimony that IQVIA Xponent is a census picking up 93 percent of all pharmaceutical transactions in the United States?

A. I have, yes.

Q. Do you agree with Professor Conti on these two points?

A. I do not, no.

Q. Why not?

A. In terms of the census, to start with that, as I just mentioned, it's a sample, so IQVIA's own documentation indicates that it's a sample that they then estimate and extrapolate the market based upon it. And so it's not a full census of the entire population, certainly not every transaction.

In terms of the gold standard, IQVIA is definitely broadly used within that context that I described, so for sales and marketing and research purposes.

The way I think of it in terms of its use is I think of it as kind of in the four corners of the data. And what I mean by that is the way IQVIA describes it should be used as well is within the dataset itself, if you're performing, you know, comparisons on market shares or you're looking at different drugs for manufacturers or different prescribers and you're trying to understand, you know, relative comparisons within that dataset because it's based on a sample that's being extrapolated, it has the same assumptions, the same extrapolation across that market. And so you can actually use it in that comparative fashion.

Where it's not the gold standard --

THE COURT: So that would be gold standard, what you

just described?

THE WITNESS: That would be, I think, referencing a gold standard, correct.

Where I think it's not a gold standard and I think where IQVIA's documentation supports that is for things like using pricing information to establish a specific fact. So for pricing information, you know, they certainly state that, you know, it's a sample under certain instances where that information is not the actual negotiating price that's being reported.

THE COURT: Is that why they say it's not intended for litigation purposes?

THE WITNESS: Yeah. Well, they exclaim that, you know, they have some documentation that will show it as well, but both in the data disclosure and some of the other documentation they caution against using it as an established fact for that. They say if you're going to use it, you should use it both in -- recognize that it's a sample that's extrapolated and then also use other information to compare it to. So it's supposed to be used in conjunction with other information, and you shouldn't use it to establish a fact, as Professor Conti does in her damages calculation.

And, frankly, the method that I applied to evaluate that, I use it in the way that IQVIA states; that is, I'm comparing it to other relative benchmarks to try and assess

whether or not it's reliable.

BY MR. OSTFELD:

Q. All right. You've made several references to IQVIA's documentation, so why don't we move to that. You've included excerpts of that documentation in your slides?

A. I have, yes.

Q. And the documentation itself is contained in the binder that we've distributed?

A. It is, yes.

Q. All right. Why don't you begin walking us through the documentation. Just make sure that you're moving us to the correct slide and giving me an opportunity to direct the Court to the correct tab in the binder, if you please.

A. Okay.

So the slide is up. This is an excerpt from the IQVIA Xponent FAQ document, the frequently asked questions. This is a public --

Q. I'm sorry to interrupt.

MR. OSTFELD: Your Honor, this corresponds to tab 1 in your binder.

THE WITNESS: I'm sorry for that.

BY MR. OSTFELD:

Q. All right. Go ahead, Mr. Gibson.

A. Thank you.

Here you can see that IQVIA is stating, and I was

about to say this is an FAQ document that is publicly available. You can download it from IQVIA's website. What it's indicating is that the Xponent dataset, as it's highlighted there in the red circles, is reported sample volume and estimated volume.

So as I was saying before, they're taking a sample from a number of pharmacies and then estimating the market volume based upon that. So this is, you know, IQVIA stating that right up front that this is a sample and these are estimates.

Q. All right. And what's next?

A. Next is an excerpt from the Published Specifications. So this is, again, a public document that IQVIA lists that provides specifications for kind of the general use of their data --

MR. OSTFELD: And, Your Honor, this corresponds to tab 2 in the binder.

BY MR. OSTFELD:

Q. Please go ahead, Mr. Gibson. Sorry to interrupt you.

A. I'm sorry.

This reinforces the other point about the Xponent data. Here you can see the underlined passage that "most IQVIA offerings are derived from the use of statistically representative samples, not a census of activity." So, again, it's just, you know, a caveat that IQVIA is providing regarding

how you might treat its data.

If you go to the next slide.

Again, this is a second excerpt from the Published Specifications.

Here, you can see there's a couple things that we point out here. Again, IQVIA indicating that "IQVIA information represents an estimate" in many instances, and then that point that we were discussing earlier that "proper practice involves the use of IQVIA information," you know, in conjunction with other information and observations in the marketplace. And so you can see that in the second underlined passage. And that's the point that I was making before when I said my methodology aligns with IQVIA's, kind of, recommendations on how you should treat or status this.

Q. All right. What's next, Mr. Gibson?

A. Go to the next slide. It's a third excerpt from the Published Specifications.

Here, again, reinforcing that some of the IQVIA information is collected through surveys and then indicating that they give some limited assurances regarding quality, you know, in that instance.

And then we now turn to the next slide.

Q. All right. Is this a new document, sir?

A. This is a new document. This is from the Data Disclosure Policy, which I think Your Honor asked me questions -- a

question before about use for litigation. I think this is the document that they put forth to talk about if you have to disclose the data to a third party.

MR. OSTFELD: And, Your Honor, this corresponds to tab 3 in your binder.

THE WITNESS: Here, a couple points that they're making in this document as well. The IQVIA data is intended to support sales and marketing research, highly reliable for those purposes. And it says although appropriate for its intended purpose of supporting business and marketing analyses, it's susceptible to error or variance and is not intended to be used as direct evidence or establish any fact.

So the way I interpret that, right, is you're looking at it, that four corners of the data analysis that I talked about, that a relevant analysis within the data as opposed to saying this number that's sitting in the dataset is an established fact and then using it that way.

BY MR. OSTFELD:

Q. All right.

A. Yeah. Oh, sorry.

Q. Go ahead. Please.

A. I was going to say, there's one additional publicly available information from IQVIA that I also included. Here, just to note, and I made the comment that the way in which the IQVIA data is reported, that summary level, is not real-world

transaction data. It's kind of rolled up and you can't individually identify individual transactions or an individual dispensing event.

Here, this is IQVIA saying something similar, right? So IQVIA doesn't list the Xponent dataset under its real-world data sources. You know, on their website, publicly available, it lists the real-world data which you can see, and I apologize this is small print. But it lists a number of different datasets which are the real-world data. And if you look at those, those are detailed transactional-level data. In some instances they talk about the ability to link between those datasets as well.

IQVIA is listed separately in an area. That's for under U.S. national data. That's not the real-world data.

Q. Mr. Gibson, for the benefit of the court reporter, you may want to slow down just a little bit.

A. Oh, I'm sorry.

Q. You're conveying a lot of information here.

All right. And the real-world data source document we've just been looking at, that corresponds to tab 4 of the binder?

A. That's correct, yes.

Q. And if you were to look in tab 4 of the binder, can you please identify where the IQVIA Xponent data source is indicated in that tab relative to the real-world data sources?

A. Yes. And so if you go to tab 4 on that first printed page, which is a printout of the website, you'll see that the Xponent data is the third bullet -- the last bullet on that third page under U.S. national data.

And then if you flip the page, you'll see that there is a real-world data section on that second page, and that's where those additional datasets that are at the transactional level are listed.

Q. All right. In addition to these published sources from IQVIA, is there any other documentation from IQVIA that you've evaluated in connection with Dr. Conti -- excuse me, Professor Conti's statement that IQVIA is the gold standard?

A. There is, yes. There's an email.

Q. Okay. And let's go to that email, which is the next slide. And I believe this corresponds to tab 5 of the binder.

A. That's correct. Yes.

Q. All right. Please tell the Court what we're looking at here.

A. This is an email from -- an email response, I guess, from an IQVIA account manager to an individual at Cornerstone. Cornerstone is another consulting firm that's retained by one of the defendants in this matter.

In this email, the IQVIA account manager is making two points that I call out. One, that the IQVIA field T price, and why that's important, T price is the field in the IQVIA

Xponent dataset that Professor Conti uses to establish pricing information.

And so the account manager is indicating that the T price field is not a standard field when it's produced. And so it's not necessarily part of its standard set of transactions. And then when IQVIA includes that T price field, they include it with this caveat that the account manager has here. And the caveat states: "Please note, a notable portion of pharmacies report list price in this field rather than the amount collected, therefore, the field should be used with that caveat in mind."

And so why that's important from my perspective is that list price is, you know, kind of recognized from an industry standpoint to be a price that -- not the actual negotiated price that the transaction occurs at and it is, in fact, a higher price.

Q. Now, Mr. Gibson, you are not yourself a party to this email?

A. I am not, no.

Q. Did you undertake any steps to authenticate this email before you evaluated it?

A. I did not, no.

Q. Did you speak with any of the parties to this email?

A. Well, I spoke with the individual from Cornerstone.

Q. All right.

A. So...
Q. Documentation of this type, unpublished but documentation that's gone to someone else, is that the kind of material in which experts in the pharmaceutical claims analysis field reasonably rely in forming an opinion on the validity of a dataset like IQVIA Xponent?
A. Yes. So any information, any caveats about a dataset is absolutely something I would incorporate when using the dataset.
Q. To be clear, are you saying it is never appropriate to use IQVIA Xponent data or other IQVIA datasets in performing a pharmaceutical claims analysis?
A. No, I'm not. I'm making the comment, as I stated before, that within the four corners of the recommended use, I think that's an appropriate use. In this matter with respect to the T price value in particular, I think that it is a limitation and it makes it unreliable given some of IQVIA's own -- given what I observed, excuse me, in my benchmark analyses, and then some of this other information from IQVIA which corroborates what I was saying.
Q. Right.

In a few minutes you'll be testifying about your own methodology that you used in evaluating Professor Conti's use of the IQVIA Xponent data in her damages calculation.

What is the relevance of the documentation we just

reviewed to your opinion and your methodology regarding the IQVIA Xponent data?

A. Yeah. It's corroborated. I mean, as I mentioned, I observed the difference in the IQVIA price and the fact that the IQVIA pricing information was an outlier based upon the benchmark analyses in my methodology. The IQVIA documentation aligns with what I observed and corroborates that.

Q. All right. Let's turn now to Professor Conti's testimony regarding point of sale and point of payment. And I believe that's the next slide.

Have you reviewed --

MR. DAVIS: Your Honor --

THE COURT: One second, Counsel.

MR. OSTFELD: I'm sorry?

MR. DAVIS: Respectfully, and I don't mean to object too much on direct, but this is outside the scope of Mr. Gibson's opinion. He testified at his deposition that he was offering no opinion that TPPs didn't pay the amount assigned to them at point of sale.

MR. OSTFELD: Your Honor, I don't think that's precisely what Mr. Gibson testified to. But Professor Conti offered a new opinion for the first time at the hearing last week that -- and it's reflected on the slide here -- that point of sale is exactly the same as the point of payment. That's not an opinion she's offered before. Mr. Gibson isn't going to

offer an opinion on when the TPPs made their payment.

THE COURT: Well, if she didn't offer it before, then she would be precluded from offering it at trial.

MR. OSTFELD: Understood, Your Honor. But for purposes of the 702 Hearing, she offered that opinion to try to indicate fit, to try to demonstrate that there was a fit between her model without the translating mechanism that Judge Kugler held would be necessary to tie her damages opinion to the class definition. So Mr. Gibson is going to speak to that issue and whether the point of sale is the same as the point of payment.

He also has offered opinions on errors with Professor Conti's use of point of sale as her frame of reference. That is in his opinion, and that's the testimony he'll be offering today.

MR. DAVIS: May I respond?

THE COURT: Okay.

MR. DAVIS: Dr. Conti has always calculated her damages based on point of sale, and it was the defendants that injected this point-of-payment issue into the case. And so Dr. Conti's testimony is not a new opinion. It's just responding to an argument the defendants had made. Her opinion has always been that point of sale and point of payment are the same thing.

THE COURT: Do you agree with that?

MR. OSTFELD: Her opinion -- no, not that point of sale and point of payment have always been the same thing. That's not her opinion. Her opinion has always been that her calculation is based on the point of sale and that what occurs after the point of sale is of no moment to her calculation. Mr. Gibson has always been critical of that opinion by Professor Conti and has certainly disclosed opinions on that. And that's what he'll be speaking to.

THE COURT: Can someone tell me where she opined that point of sale equals point of payment?

MR. DAVIS: Well, it's inherent, Your Honor, in her report. She says that the TPPs are damaged at the point of sale and by incurring an obligation which is, under our case law, the same thing as a payment.

And so for her the point of sale is the moment both in time and place of damages. And the fact that a TPP may have, you know, made good on paying that amount like a week later when it bundles a bunch of claims and pays them is of no moment, and it's more of a legal issue, Your Honor.

There's law going back to the foundations of this country that it's valid -- like a promise to pay is valid consideration. It's the same thing as payment.

And so I don't think anyone here disputes that at the time a consumer walks into the pharmacy counter and that live adjudication happens of the consumer's share and the TPP's

share, the TPP is obligated to pay that share that's assigned to them.

THE COURT: So she is opining the point of sale is the same as point of payment?

MR. DAVIS: Yes, Your Honor. It's inherent.

THE COURT: Even though she didn't explicitly say it. She inherently said it; is that what your position is?

MR. DAVIS: Well, I mean, it is -- I mean, again, I think we have to trace back to how this issue was raised in this case. It was raised by the defendants. This is a defendant saying, hang on, well, they didn't actually pay at the point of sale, but they were obligated to pay. And that's inherent in her analysis; that point of sale is the appropriate moment both in place and time to measure -- to measure damages, is because they were obligated to pay there. And Dr. Conti goes through, you know, I think she does have in her report, you know, how pharmacy claims are adjudicated.

THE COURT: So why isn't he permitted to rebut that?

MR. DAVIS: Well, I don't think -- but it's not part of his -- he is a rebuttal expert witness.

THE COURT: Right.

MR. DAVIS: And he rebuts certain of her opinions, but that's not one of them. I questioned him at his deposition that he was not taking issue with the fact that TPPs, in fact, do pay the amount assigned to them at the point of sale, and

Mr. Gibson told me that he wasn't offering any opinion on that.

THE COURT: When did this issue arise?

MR. OSTFELD: Your Honor --

THE COURT: After her testimony?

MR. OSTFELD: Well, two points, Your Honor. First of all, Mr. Gibson has always criticized Professor Conti's point-of-sale analysis. That's the entire underpinning of his Opinion 2 that he'll be discussing today.

THE COURT: Is that true?

THE WITNESS: That is true, yes.

THE COURT: Okay. Can you show me in your report where?

THE WITNESS: Yes. Correct, it's in here.

THE COURT: You folks can't agree on what the reports even say. So let's find it.

MR. DAVIS: May I address that?

MR. OSTFELD: May I approach the witness, Your Honor, and give him copies of his report?

THE COURT: No; I want him to answer my question.

THE WITNESS: Oh, sorry.

So I'm just trying to pick out one section, but --

THE COURT: You can just tell me. I'll read it myself, if you don't mind.

THE WITNESS: Okay. So, one portion of my opinion is that the opinion A in my -- this is the July 17th report, I

believe, is that Dr. Conti's measure of damages is fundamentally unreliable because it ignores the Medicare Part D drug payment structure process. That opinion is that there are things that occurred after the point of sale. These are payments made -- sorry, these are payments made by CMS to the --

THE COURT: Do you explicitly say that?

THE WITNESS: I explicitly say that.

THE COURT: Where? Show me where.

THE WITNESS: Okay.

THE COURT: What's the question he was asked at the deposition?

MR. DAVIS: Well, respectfully, Your Honor, it's a different issue. These Medicare payments that he's -- these Medicare payments that occur after the point of sale, that's a different issue from the moment in time where the payment or, you know, where TPPs are damaged. It's a different issue.

I mean, yes, he --

THE COURT: Can I just ask a very fundamental question? Are we really talking about a whole big difference between the point of payment and point of sale?

MR. SLATER: No, we're not.

THE COURT: Didn't this come up when Conti testified? It's just not that big of a difference, for the most part. And so, I just feel like I'm spending an awful lot of time about an

issue that's just not that material to this case. And it comes under the category of "let's just argue for the sake of arguing" category.

MR. OSTFELD: We --

THE COURT: So someone answer that question for me. How significant and material is it to this case? Because you folks can have your experts argue about it and whether the jury understands it or not is entirely up to them.

MR. OSTFELD: So, respectfully, Your Honor, it is significant in two respects.

THE COURT: Okay.

MR. OSTFELD: First, it is significant because of how classes have been defined. Classes are defined by reference to where the TPPs paid any amount of money for the purchase of valsartan.

THE COURT: Okay. But that will be taken care of at class time.

MR. OSTFELD: I'm sorry?

THE COURT: That will be taken care of at, you know, class time.

MR. OSTFELD: Well, I don't know that it can be because that was Judge Kugler's ruling, is there needs to be a translating mechanism to get from the point of sale to where they paid any amount of money for the prescription drug.

THE COURT: Right. But that assumes that they aren't

one and of the same.

MR. OSTFELD: Right. Which is exactly what the opinion that Professor -- excuse me, that Mr. Gibson challenges of Professor Conti.

THE COURT: I understand. But I'm just saying how many -- is it that big of a distinction?

I mean, if you folks stand before this jury and the evidence -- I'm just going to make it up -- shows that in 99 percent of the time the point of sale is the same as the point of payment and we are spending hours and hours talking about the 1 percent and the need for a translating mechanism, I think -- I don't know what I will do.

MR. SLATER: Your Honor.

MR. OSTFELD: Your Honor.

THE COURT: No.

MR. OSTFELD: It's not that, Your Honor.

From a geographic standpoint, that's not the issue because almost every TPP pays through a PBM, then the TPP pays the PBM. So where it pays is completely disconnected geographically from the point of sale in most instances. But there's a separate -- a second concern that Mr. Gibson is addressing, and this is the portion of his report he's referencing to, is damages don't end at the point of sale. And that's the crux of his testimony.

There are many, many adjustments that take place post

point of sale that affects the amount the TPP actually pays, the amount it's obligated to pay, which is the term in which Professor Conti expressed it, and the amount that it actually pays. And the issue he is specifically centered on is CMS payments, which address more than half of Professor Conti's -- both of her payment calculations.

CMS pays subsidies that are intended to capture 74.5 percent of the drug price that is paid for covered members' prescription drugs, which means that Professor Conti's calculation by focusing on the point of sale represents a windfall of three times, three to four times the actual amount paid by the TPPs for their prescription drugs.

That's the crux of the point-of-sale controversy. That's the crux of what Mr. Gibson's testimony is going to be today.

MR. SLATER: I apologize, Your Honor. I thought -- I was just going to say, we agree with Your Honor. It's a tempest in a teacup. And we understand they're going to make this argument. We're not saying they can't. We have other arguments, collateral source, et cetera. But in terms of the point-of-sale question you asked, we agree with you, there's not enough difference that we should be battling about it today, and we do agree.

THE COURT: So you withdraw the objection?

MR. SLATER: We withdraw the objection.

THE COURT: Okay. Go ahead.

THE WITNESS: I'm sorry, Your Honor. Did you want me to point out --

THE COURT: No. The objection is withdrawn.

MR. OSTFELD: Your Honor, may I approach and take that binder back?

THE COURT: Yes.

BY MR. OSTFELD:

Q. All right. So, Mr. Gibson, we'll accelerate this portion of the discussion, but let's move quickly through this particular issue.

So you've analyzed Professor Conti's testimony that the point of sale is exactly the same as the point of payment?

A. I have, yes.

Q. Do you agree with her on that?

A. I do not, no.

Q. And why not?

A. Because after the point of sale, there are additional payments that may occur that reduce and alter the amount that's recorded as an initial potential obligation for third-party payors and may adjust that adjudication.

Q. All right. Moving to the next slide.

Could you please explain to the Court what you mean when you say that there are events that happen after the point of sale that adjust the amounts paid by the TPP at the point of

sale?

A. So I show on slide 15 on the left-hand side is the point of sale, and there you can see that as the patient, just take, for example, patient presents their prescription at the pharmacy, the pharmacy then will check the coverage, make sure the patient has a complete benefit, the patient at that time may make a copay or coinsurance payment if one is required, and then the pharmacy will issue a claim to either the PBM or the third-party payor. Most TPPs, many certainly have PBMs that help them manage the pharmacy benefit and oversee the network of pharmacies. That's the initial adjudication.

Subsequent to that, the claim goes to the PBM. At that point the PBM may make a payment to the pharmacy on behalf of a third-party payor, and then the PBM may then at some later point bill the third-party payor. And the third-party payor then would reimburse the PBM based upon those kind of usually batch claims.

Both pricing claims adjustments may happen during that process and then importantly to my opinion, as I show in that post point of sale on slide 15, CMS at that point -- so for the Part D program, Professor Conti's damages calculation, as was just stated, includes either a 58 percent or 56 percent of her damages related to the Part D program, so that's why this is germane from my perspective.

CMS at that point then may make payments and

subsidies to the third-party payor after that point of sale and that aren't even determined in some instances directly at the point of sale. They're not finalized until after that occurs, and certainly the payment wouldn't occur until after the point of sale.

And so part of the issue I have with Professor Conti's focusing on the point of sale for her damages calculation was always that it ignores everything that's happening subsequently to that, which can significantly and does significantly impact the amount that the third-party payor pays for valsartan.

THE COURT: And were you able to put a dollar value on that?

THE WITNESS: In specific instances, yes. So I was able to estimate in instances where sometimes it's 100 percent reduction. So there are subsidies that are paid by CMS to the third-party payor that may completely cover the entire cost, and that's at a transactional basis. So I just wanted to reemphasize, we talk about a real-world transactional data. My analysis is isolating specific claims in the pharmacy data, specific claims in the MSP claims data and matching that to CMS information that then shows that up to a hundred percent in some instances of that can be covered on a specific transaction, and not always a hundred percent, but certainly up to a hundred percent, and then other times it can be lesser

amounts. But certainly significant amounts that need to be accounted for from that perspective.

BY MR. OSTFELD:

Q. Now, Mr. Gibson, I know that you came prepared today to provide documentation to support your point that the point of payment occurs after the point of sale. In the interest of time, I think what I'd like to do is just very briefly touch on those items, but I don't think this is a controversial point so I think we can move through them very quickly. If you could please take us quickly through those slides.

A. Yes.

Slide 16 is guidance from CMS that reinforces that the third party is not required -- the third-party payor is not required to make payment at the point of sale in that the adjudication at the point of sale eventually drives payment which is, you know, consistent with what I was just describing.

Q. Okay.

A. Slide 17 is the CFR guidance as it relates to the Part D program which, again, indicates that that payment may occur up to 14 or 30 days after the adjudication at the point of sale. And this is specific to the Part D program which, again, is 58 to 56 percent of Professor Conti's damages calculation.

Q. Okay.

A. And then slide 18, for the portion of Professor Conti's damages calculation that's not related to Part D, there's still

guidance out there. This is state statutes for Florida and Texas. I selected those two because those are the two highest states for which Professor Conti calculates damages that also indicate that the payment doesn't have to occur at the point of sale and may occur either, you know, 30 days or 18 days, depending on the statutes you're looking at.

MR. OSTFELD: Your Honor, just for the record, those items, those slides correspond to tabs 6 through 9 of the binder.

THE COURT: Okay.

BY MR. OSTFELD:

Q. Now, Mr. Gibson, in preparing your opinions in this case, have you also had occasion to review the deposition testimony of the corporate representatives of the two assignors to MSP, EmblemHealth and SummaCare?

A. I have, yes.

Q. And have they offered testimony regarding the distinction between the point of sale and the point of payment that is illustrative of the distinction you've drawn today?

A. They do, yes.

Q. Let's move to the next slide which corresponds to tab 10 of the binder. This is testimony from Margaret Finn, the representative of EmblemHealth?

A. That's correct, yes.

Q. How is this testimony illustrative of the distinction

you've drawn between point of sale and point of payment?

A. It's consistent with the process I just described. So on slide 19, on the right-hand side, you can see Ms. Finn's response is laying out that same process at the point of sale. The member goes to the pharmacy, the member may make a copayment for insurance. The claim is sent to in this case Express Scripts, which is the PBM for EmblemHealth and then Express Scripts on a weekly basis is sending a bill. The third-party payor, EmblemHealth, is paying Express Scripts.

One wrinkle that Ms. Finn does add here that I would mention is she calls out ASO clients. So I think the process I've discussed so far would involve, you know, a pharmacy, a PBM, a third-party payor. In an ASO instance there's an additional party involved which can be the -- again, ASO, I'm sorry, means the administrative services organization. And in that instance the third-party payor is operating in an administrative capacity effectively adjudicating claims and overseeing a pharmacy network on the behalf of usually a large national -- a large employer group which could be multi state or home. And in that instance the third-party payor then subsequently is going to invoice the ASO client here, the large employer, and then the large employer is going to reimburse them. So it's adding just sort of another layer to that process as well.

Q. So in the case of an ASO, is the TPP itself just a

passthrough entity as far as the stream of payments goes?

A. In terms of the risk of those claims, yes.

Q. Okay. Turning to the next slide, this is additional testimony from Ms. Finn. How is this illustrative of the distinction you've drawn?

A. Here Ms. Finn is calling out something that aligns with my Opinion 2, so the opinion I was just talking about, where CMS provides subsidies and payments to the third-party payor. So here Ms. Finn is talking about how subsequent adjustments or payments impact what's happening at that point of sale. And here she's calling out, specifically the LICS, which means the low-income subsidy, low-income cost subsidy payment. And so that low-income cost subsidy payment is a payment that CMS makes -- and CMS being the Centers for Medicare & Medicaid Services -- makes to the third-party payor when there's a low-income individual that is an additional payment. So they're basically providing, effectively, additional subsidy and additional protection to the third-party payor to reduce their cost when they have a low-income individual.

And here she's calling out the fact that after the fact, up to a month or two later, there can be adjustments to the low-income cost subsidy status that then get addressed. And so, again, just putting that point at which the amount the third-party payor actually is responsible and owes, you know, even further back.

Q. All right. Finally, Mr. Gibson, if you could turn to the next slide which corresponds to tab 11 of the binder. This is testimony from Tiffanie Mrakovich, the representative of SummaCare?

A. That's correct, yes.

Q. What does she have to say about point of sale and point of payment that's relevant to the distinction you've drawn today?

A. It's very similar, but from the SummaCare perspective. So, again, Ms. Mrakovich is outlining that same process with the member going to the pharmacy, a claim being submitted to the PBM, the PBM billing the third-party payor, and the third-party payor then paying that. In this case its net impact with SummaCare's PBM. But she's talking about that same process from the SummaCare perspective.

Q. All right. Mr. Gibson, are Professor Conti's damages calculations based on the point of sale or the point of payment?

A. The point of sale.

Q. And has Professor Conti offered any translating mechanism to get from the point of sale to the point of payment?

A. She has not.

Q. And your Opinion No. 2 also criticizes this approach from the standpoint of CMS subsidies?

A. It does, yes.

Q. All right. And we'll turn to that in a moment, but first

let's go back to Opinion No. 1 and plaintiffs' methodological challenges to that.

So with respect to your opinion that Professor Conti's damages calculations are inflated by her reliance on IQVIA Xponent data, let's begin, could you please provide the Court with a brief overview of the substance of that opinion?

A. Professor Conti in her first class-wide damages calculation uses IQVIA Xponent data for both the volume and the pricing information. The pricing information in IQVIA is inflated compared to other relevant benchmarks and therefore is unreliable.

Q. Okay. You've just referenced "benchmarks." Let's go to the next slide.

Could you please describe the methodology you used in formulating Opinion 1?

A. So my methodology starts with a replication of Professor Conti's damages calculation. So I'm using the same inputs and then using her logic to ensure that I can get the same outputs. The reason why that's important is as I mentioned, for example, the IQVIA data is summary level, and sometimes the outputs from the calculation are also summary level, but that enables me to pause the calculation output intermediate datasets and other sometimes transactional level detail that I can then use for comparisons.

Then, as I mentioned for Opinion 1, my methodology

relies upon a benchmark analysis where I compare the IQVIA information, which, just to restate, is sample information that's reported at a summary level to other detailed real-world transactional datasets, you know, the pharmacy claims and the MSP claims data and some Part D specific information, where I can actually look even on a transactional level and make comparisons to understand how the IQVIA data compares to that level of detail.

And then for the third piece is just that consistency check to see if those benchmarks against IQVIA, how they're aligned.

Q. Mr. Gibson, why did you select this methodology to evaluate Professor Conti's use of the IQVIA Xponent data?

A. This is the type of approach that I would use in evaluating pricing and other information with my clients and my consulting group.

Q. All right. Let's go through each step of the methodology you've just described beginning with step one of the replication of the calculation, and I believe this is the next slide.

Please describe how you replicated Professor Conti's calculations.

A. Yeah.

And so Professor Conti, as I mentioned, it's using her inputs and her logic. The basic of the calculation is in

her first calculation, which is the -- she uses IQVIA Xponent data for both the volume and the pricing information, so both sides of that, and it's basically volume times price, and that equals the damages. In that instance, she calculated damages of 1.3 billion.

In her second calculation, she still uses IQVIA Xponent data for the volume information, but replaces the pricing information with pharmacy claims data. And that's the detailed transactional level dataset that we can talk about more. In that second calculation she calculated damages of 319 million.

Q. And were you able to successfully replicate both of her calculations?

A. Yes.

Q. All right. So turning to the explanation for this delta of a billion dollars between the two calculations, let's go to step two. Could you please describe, and that's the next slide, could you please describe your benchmarking analysis?

A. So I benchmark IQVIA, which I don't overstate it, is summary level against datasets that include transactional level detail that I can actually see the individual negotiating prices as well, as well as one dataset that it's a summary of the transactional detail.

Here the three sets of data that I used for benchmarks are, first, the MSP claims data. So that's the

claims data produced by MSP for EmblemHealth and SummaCare.

The second set of data is that pharmacy claims data that Professor Conti also used in her second class-wide calculation. That's nine pharmacy -- nine chain, large chain pharmacies and about 600 transactions -- 600 million transactions, excuse me.

The third set is CMS Part D data. And that actually consists of two components. One is detailed transactional data, what's referred to as prescription drug event, or PDE data. That, again, is, you know, individual dispensing events and detail the individual, the date, the negotiated price, what was dispensed. It can actually even be tied back to these other datasets.

And in the second component there for the CMS data was summary level information, but it's summary-level census information because it's the summary event PDE data. So that PDE data, every single MAPD plan and PDP plan has to submit that data to CMS, and CMS takes that data, so it's a census of the entire Part D program and imports it in what they call their "Part D dashboard." So I was able to use that and understand what the pricing levels were across the entire Part D program.

Q. Mr. Gibson, why did you select those three specific data source as your benchmarks against the IQVIA pricing data?

A. Well, for MSP claims data and pharmacy claims data, those

are all datasets that Professor Conti used to calculate -- make the damages calculations. So she performed a damages calculation separately for EmblemHealth and SummaCare using MSP claims. And she also, as I described before, performed a class-wide calculation using the pharmacy claims data. And then those are both at a detailed transactional level as well.

And then for CMS, given that Professor Conti's 58 percent or 56 percent of Professor Conti's damages relate to the Part D program, I thought was important to use a specific CMS benchmark.

Q. Okay. Let's go briefly through each of the benchmarks to give the Court a sense of how you performed your comparison and what you found.

Beginning with the MSP claims data benchmark, you've already described what the MSP claims data is and why you selected it. This was one of the datasets you said Professor Conti used?

A. It is, yes. Professor Conti performed a separate damages calculation for SummaCare and EmblemHealth.

Q. And what is the value of using the MSP claims data specifically as a benchmark against the IQVIA data?

A. Well, one, it's a census for SummaCare and EmblemHealth in terms of their Part D. So everything -- the data that was produced for them was their Part D data. And so you can see exactly for those plans, these individual third-party payors,

what the damages would be using their own claims data and is transactional level detail.

Q. All right. Now, how did you actually go about -- and this is the next slide -- how did you actually go about comparing the IQVIA Xponent dataset with the MSP claims dataset?

A. Yeah. And I won't -- I know this is a lot on the slide. This is just showing the IQVIA data fields and the MSP data fields, and it's just to be able to demonstrate that, one, the IQVIA data is summary, but I'm able to match within the IQVIA data and isolate, for example, using that plan name field highlighted in purple, the EmblemHealth and SummaCare-related transactions and then compare that to their own MSP claims data, which as you can see is a much more detailed dataset and provides that transactional level of detail.

Q. Now, turning to the next slide, can you please explain -- you said that you were able to narrow this down to the Emblem and SummaCare specific data within the IQVIA dataset. How are you able to do that to perform an apples-to-apples comparison?

A. Yeah. And slide 28 is an excerpt of the programming logic that I used for some of that comparison. And the key point to see there is just where it's highlighted in blue is the plan name, and so it's focusing on SummaCare in this case. And then that MOP is a value that sits in the IQVIA data that indicates that is Medicare Part D. So that's just demonstrating how I isolated the transactions of the IQVIA data.

Q. And for those of us who don't necessarily program in Sequel, can we bottom line that and essentially say what you were comparing the MSP claims data to in the IQVIA dataset?

A. Yeah. So because I isolated the IQVIA data to the specific plan and only the Part D portion, it's an apples-to-apples comparison of the IQVIA data and the MSP claims data which was the Part D data for SummaCare and EmblemHealth.

Q. All right. What did you find when you compared those two datasets?

A. If we flip to the next slide.

For SummaCare, for example, I found that the IQVIA data was overstated by about 60 percent. I did two comparisons, both on a per-unit and a per-claim basis. On a per-unit basis, 61.7 percent. And per-claim, 60.1 percent when you take it across all years.

Q. All right. And what about with Emblem?

A. And then if we go to the next slide for EmblemHealth, same. I also found that the IQVIA data overstated the EmblemHealth prices in this case by approximately 70 percent. I did the same per-unit and per-claim comparison. On a per-claim basis, 73.8 percent. On a per-unit basis, 69.5 percent.

Q. All right. Now, you mentioned that Professor Conti performed her own damages calculation for MSP using the same

MSP claims data. Did you compare her calculation using the MSP claims data against her calculation using the IQVIA dataset?

A. I did, yes.

Q. All right. And is that the next slide?

A. It is.

Q. All right. What did you find when you compared her two damages calculations using the two different datasets?

A. Yes. Professor Conti's IQVIA calculation is four times as high as the calculation she performed using those MSP-specific datasets, and that's across both SummaCare and EmblemHealth, as you can see there on slide 31.

Q. All right.

THE COURT: Remind me how she squared those numbers.

THE WITNESS: I'm sorry, Your Honor?

THE COURT: How did she reconcile the distinction?

THE WITNESS: I don't think she has. I'm not aware of her reconciling the distinction.

THE COURT: And she didn't explain it either in her report?

THE WITNESS: She doesn't address that in the report.

THE COURT: Go ahead.

MR. OSTFELD: All right.

BY MR. OSTFELD:

Q. Thank you, Mr. Gibson.

Let's move to the second benchmark. This is the

pharmacy claims data benchmark.

A. So the second benchmark, I used the pharmacy claims data. Just to restate, that is transactional level detail for the nine large pharmacy chains that make up approximately 70 percent of the U.S. market.

And there, it's transactional level detail and about 600 million valsartan transactions contained in that claims data.

Q. So this was a much larger dataset than the MSP claims dataset?

A. That's correct, yes.

Q. So why did you select the pharmacy claims data as one of your benchmarks against the IQVIA dataset?

A. Well, two reasons. One, it's also a dataset that Professor Conti used to calculate damages in which she calculated 300 million versus her 1.3 billion using IQVIA. And then --

THE COURT: But --

THE WITNESS: I'm sorry.

THE COURT: Because, you know, remind me again what she was trying to do, why she was analyzing the pharmacy claims data and the MSP data vis-a-vis the IQVIA data.

THE WITNESS: The IQVIA data, so in Professor Conti's --

THE COURT: Because if I'm understanding what you're

saying is they are worlds apart. So remind me what she said in her report as to how she explains away the pharmacy claims data and the MSP data.

THE WITNESS: I'm not aware of her having any explanation for the MSP data. The pharmacy claims data she -- I won't say she explained it, but she cites differences in what she believes are the sample populations between IQVIA and the pharmacy claims for the difference.

Now, I don't agree with that, because, as we'll talk about with my benchmarking analysis, the pharmacy claims data, the MSP data, the Part D data were all relatively consistent in my benchmarking.

THE COURT: Which you would expect?

THE WITNESS: Which you would expect.

THE COURT: Which you would expect.

THE WITNESS: And the IQVIA data was a significant outlier. It was, you know, 76 percent higher. And so, you know, I don't agree that the difference between IQVIA and the pharmacy data, you know, calculations, because the pharmacy data doesn't have the right distribution in the sample basically as she's talking about.

THE COURT: All right. Go ahead.

BY MR. OSTFELD:

Q. All right. So, Mr. Gibson, could you please again, as you did with the MSP claims data, could you demonstrate briefly how

you went about comparing the two datasets to one another?

A. Yes. Go to the next slide.

Q. Which is the next slide.

A. So, again, I know there's a lot of information here, but similar to the prior slide, on the left-hand side it's the same IQVIA data fields. The right-hand side is an example of one of those pharmacy datasets. So there are nine different datasets. Each one has a different structure and format. This is Walmart, but it's the same process. Within that data I can isolate and compare a product. The IQVIA had that kind of monthly roll-up level, but then actually see the individual related Walmart pharmacy claims data transactions and make comparisons across that.

Q. And what did you find when you compared the IQVIA pricing data as a benchmark against the -- excuse me, the pharmacy claims data as a benchmark against the IQVIA pricing data?

A. So if we go to the next slide you'll see that on a weighted basis, that difference is 76 percent. And that weighted just means the price difference weighted by the volumes used in Professor Conti's damages calculation. And, frankly, that's just the difference between her 1.3 billion IQVIA calculation and her $300 million pharmacy claims-based data calculation. If you unweight it, it's about a 64 percent difference.

Q. All right. And that dollar difference, that's the next

slide. In quantitative terms, what is the dollar difference between Professor Conti's two calculations using the IQVIA pricing data as compared to the pharmacy claims pricing data?

A. It's approximately a billion dollars.

Q. All right. Turning now to the third benchmark, the CMS Part D benchmark.

What is the CMS Part D data? I know you discussed this earlier, but this is kind of complicated so I want to give you a chance to walk through it a little more slowly.

A. Yeah. It consists of two pieces of information. One, which is the second bullet listed here on the slide, the PDE data, which is that prescription drug event data. And just to restate, that's data that CMS mandates. Each and every third-party payor involved in the Part D program submits to them the detailed transaction. So for every single transaction, every single dispensing event, you have to send PDE data that represents that to CMS so they could use that in tracking and managing the cost for each third-party payor. It's also then used for CMS to help determine those subsidies and other payments that they're making to a third-party payor as well. And so that's something that every single plan has to submit.

The second piece is that CMS Part D dashboard information, which is the aggregation of that PDE data across all the entire Part D program. And the reason why they use

that as well is I only had PDE data for SummaCare and EmblemHealth. And so I could perform specific comparisons on SummaCare and EmblemHealth with the PDE data, but then across the Part D program, the dashboard information was necessary.

Q. All right. And just to make sure we understand, the Part D dashboard you're referring to, that represents 100 percent of the population of Part D transactions?

A. Yeah. It's a census of the Part D program.

Q. Okay. So, how did you go about comparing the IQVIA Xponent data and the CMS Part D data?

A. So on the -- as you can see here, on slide 37, if you go to the next slide. Sorry.

You can see the comparison for across from 2013 to 2018 and see that the IQVIA information on a product basis overstates the Part D prices that were reported by 43 percent to 74 percent on a per-unit basis.

Q. Okay. So you compared the average prices from the IQVIA dataset each year against the average prices from the CMS Part D dashboard each year?

A. That's correct, each year and for the analogous products.

Q. And then did you provide an aggregate analysis as well?

A. I did, as shown in the graph.

So for valsartan, it's about a 54.5 percent difference across the years. And for valsartan-HCTZ, it's about a 57.1 percent difference.

Q. Okay. Let's move to step three of your methodology, the consistency check, and this is the next slide.

Could you please describe the consistency check that you performed after your benchmarking exercise?

A. So the consistency check consists of looking at each of these and seeing how they align. So as I mentioned, the EmblemHealth and SummaCare, MSP claims data, IQVIA was about 60 to 70 percent higher than that. The pharmacy claims data, IQVIA was about 64 to 78 percent higher than that. And against the CMS Part D data, IQVIA was about 45 to 75 percent higher than that. And so in each case, higher in similar orders of magnitude.

I'll also mention that, and, you know, we can talk about it in my next opinion as well or in some subsequent analysis, that I can also trace individual transactions across some of these datasets, from EmblemHealth, SummaCare claims data, pharmacy claims data to PDE data.

Q. And what did you conclude from your consistency check?

A. I concluded that the IQVIA data was an outlier and that pricing was not consistent with the other datasets and therefore it's not reliable to use in a damages calculation.

Q. All right. Now, you've read --

THE COURT: Have you ever been involved in any litigation where the damages calculation was done relying upon the IQVIA data?

THE WITNESS: No, I have not been involved in a litigation where a damages calculation was involved using IQVIA data, no.

BY MR. OSTFELD:

Q. All right. Now, Mr. Gibson, you've read plaintiffs' motion seeking to exclude your opinions?

A. I have, yes.

Q. And you're aware that they have criticized each of the benchmarks that you analyzed in this case?

A. I am, yes.

Q. All right. Let's go through their major criticisms, and that's the next slide.

So with respect to the MSP claims dataset, they said that it is not an apples-to-apples comparison between the IQVIA dataset and the MSP claims dataset. Is that a valid criticism?

A. No, it's not.

Q. Okay. Why not?

A. For the MSP claims data, as I showed in the Sequel logic, I'm comparing the specific MSP claims data that represents Part D to the specific transactions related to either SummaCare or EmblemHealth and only for Part D in that comparison. So basically their allegation is that it wasn't apples to apples because I wasn't looking at Part D data in both instances. I was looking at the Part D data in both instance. I applied the logic to IQVIA data to isolate Part D for SummaCare and Part D

for EmblemHealth and compared SummaCare Part D to SummaCare, MSP claims data which is only Part D and then the same thing for EmblemHealth. So it's apples to apples.

Q. With respect to the -- well, let's skip to the CMS data. They said it fails to compare Part D -- that you failed to compare Part D pricing to commercial pricing. Is that a valid criticism?

A. No, it's not.

Q. And why not?

A. Well, there is no reason for me to compare the Part D pricing to commercial pricing. As I mentioned, I wanted to focus on the comparison of Part D to Part D, because Professor Conti's calculations are 58 or 56 percent focused on Part D, and so that's the appropriate comparison because those are the overlapping transactions. I don't know why I would compare the Part D to the commercial.

Q. And with respect to the pharmacy claims data, and you alluded to this earlier, the ways that Professor Conti differentiates between the two datasets. The plaintiffs have indicated that the pharmacy claims dataset is incomplete, over-representative of big box and grocery stores and over-representative of mail order. Do you agree with those criticisms?

A. I don't, no.

Q. And why not?

A. Well, each of those criticisms is based upon the assumption that the IQVIA data is, one, a census, that it represents the entire market, and, you know, as IQVIA states, the IQVIA data is a sample that's been extrapolated to represent the market.

But as I've testified, they also provide qualifiers on that and provide qualifiers not to use that extrapolated amount in exactly this manner and say, okay, this represents the absolute market and any comparison against it is not representative.

Q. Okay. And anything else?

A. No, sir.

Q. Okay.

Now, Professor Conti last week also testified to a convergence effect; that as the volume of the pharmaceutical claims dataset begins to approach the IQVIA reported volume, that the results converge in terms of pricing. Do you agree with that analysis?

A. I don't agree, no.

Q. All right. Let's move to the next slide. And can you explain why you disagree with Professor Conti on that point?

A. Professor Conti performs that analysis by aggregating the Teva, Torrent and ZHP information together to attempt to demonstrate that there is a convergence and a trend in this left-to-right movement.

If you disaggregate that, which I think is the more appropriate way to look at it, because that's the level at which those prices are set by the manufacturer, you'll see that that relationship doesn't hold.

So, for example, looking at Teva, you can see that as you look at the X axis there, which is the percentage of pills as a percentage of -- if you assume the IQVIA total is the total of pills, and then on the Y axis how the price is aligned, you can see that it's a flat line. And that basically indicates that there's no relationship. So when we disaggregate these by a manufacturer, you don't see that one-to-one kind of convergence that Professor Conti indicates.

Q. All right. Mr. Gibson, let's move on to your Opinion No. 2 relating to the CMS subsidy issue.

A. Can I grab a quick sip of water? I'm sorry.

Q. Oh, please.

Let's begin again with a summary of the opinion that you anticipate giving at trial regarding CMS subsidies.

A. So Professor Conti's damage calculation is overstated and unreliable because it does not include payments that CMS makes to the third-party payors that reduce the total amount paid by the third-party payor. So those are those subsidies that we were discussing before that occurred, you know, after the point of sale. She focused on point of sale amounts which don't incorporate any of these subsidies or payments.

THE COURT: None of them?

THE WITNESS: None of them.

THE COURT: Okay.

BY MR. OSTFELD:

Q. So moving to the next slide, Mr. Gibson, could you please describe the methodology that you used in formulating Opinion No. 2?

A. So similar to my Opinion No. 1, my methodology starts with the replication of Professor Conti's calculation, again, using the same inputs, using her same logic, and that again enables me to output interim datasets and detail that I can use for detailed transactional-level comparisons.

Here, at step two, the focus is that transactional-level comparison combined with looking at the CMS guidance specific to those subsidies. So I referenced the CMS guidance regarding the low-income subsidy and the catastrophic subsidy and the direct subsidy to make certain that I'm applying and viewing those in the appropriate way, and then by taking detailed transactional-level detail, again using that PDE data to compare to other transactional-level detail so I can actually match it and say, okay, here's a transaction where Dr. Conti identifies a damage amount based upon the negotiated price and here's the matching transaction in the PDE data, for example, that shows where CMS would have paid a subsidy that reduces the third-party payor's amount.

Q. All right. So, Mr. Gibson, again, let's go through each of the steps. I think we can move through step one pretty quickly. Your replication of Professor Conti's calculations, was that essentially the same replication you've described with respect to Opinion No. 1?

A. Yes, it was.

Q. And when you replicated Professor Conti's calculations, did you find any accounting for CMS subsidies as part of her calculation?

A. Professor Conti does not account for the subsidies.

Q. And is that true of both of her calculations, both of her class-wide calculations?

A. It's true of both of her -- it's true of all of her classifications both for class-wide --

THE COURT: May I ask a question? Do you agree with that; that she does not account for the subsidies?

MR. DAVIS: Yes, I agree with that. We have arguments, legal arguments as to why these are collateral source and/or that the subsidies aren't even traceable to valsartan. And I'll explore some of this on cross with Mr. Gibson.

THE COURT: Okay.

(Counsel conferring.)

MR. DAVIS: Yes. And let me rephrase. It's not that she didn't account for it. She just didn't believe that it was

an appropriate thing to include in the damages analysis.

THE COURT: If someone gets reimbursed or someone gets a subsidy, that comes off of what's owed you, just as a matter of compensatory damage law. So I'm kind of a little bit lost why it would not be relevant that the TPPs didn't incur these costs, but they would be then getting a windfall, wouldn't they?

MR. SLATER: Your Honor.

THE COURT: Yeah.

MR. SLATER: Our legal argument is that at most that would be a collateral source, and that at most Your Honor would mold the verdict after the verdict if Your Honor finds that there is competent evidence from which you could make such setoffs, but that it's not something the jury would consider because it's a collateral source.

And I think it's the *HIV* litigation case actually the judge set forth a process by which that was done, where after the trial the judge said that the judge would look at the damages afterwards and then approve or not approve a molding process and handle it from the bench as opposed to the jury handling it because of the collateral source rule.

THE COURT: Do you agree with that?

MR. OSTFELD: Absolutely not, Your Honor.

THE COURT: Oh, what a shock.

Look, we'll brief it later. Has this even been

briefed?

MR. OSTFELD: It has, Your Honor.

MR. STANOCH: Yes, Your Honor. We cite the cases in our *Daubert* motion on Mr. Gibson at page 6, *In Re HIV* case, and *In re Zetia,* in which Dr. Stiroh, who tried to make the same offset argument about Medicare monies, was precluded from arguing or presenting any evidence or argument to the jury about the same subsidies that Mr. Gibson is talking about here.

THE COURT: So a jury comes back with a verdict and then I reduce it by the amount of the subsidies?

MR. STANOCH: Yes, in a post --

THE COURT: So why don't you folks just agree what the subsidies are, because I'm going to reduce it anyway.

MR. DAVIS: Well, Your Honor, there's also --

THE COURT: Why are we arguing about something we don't need to argue about?

MR. DAVIS: Well, we don't agree that they should be reduced at all.

THE COURT: You just told me it's a collateral source and that I have the ability to reduce the verdict.

MR. DAVIS: Well, if Your Honor determines that reduction is appropriate. But under the collateral source rule, they shouldn't be reduced at all because the -- and I'll cite to you the *Craig vs. Y & Y Snacks*, Third Circuit case, and that was in our *Daubert* briefing as well, that involves by

analogy a worker who is wrongfully terminated and then received unemployment benefits from the state. The defendant said, wait a second, you know, the plaintiff got unemployment benefits, they shouldn't be able to recover the full amount of their damages because they got those benefits.

The Third Circuit said, no, if there's anyone who's going to, you know, the defendant -- the wrong -- the defendant who's in the wrong here shouldn't get to benefit from the fact that by happenstance the plaintiff later in time receives some benefit from that. And that's our --

THE COURT: I'll have to take a look at it. Okay. Let's just move on.

MR. OSTFELD: Okay. Thank you, Your Honor.

THE COURT: All right. They pretty much agree that Conti didn't consider the subsidy analysis and that it will be up for the Court. So we probably don't have to spend a whole lot of time on this. Intuitively it seems as if the subsidy should be, you know, be given credit for, but we'll have to brief it. So can we move past this.

MR. OSTFELD: I'll move through it quickly, Your Honor. We do have a disagreement in the briefing as to whether this should be presented to the jury.

THE COURT: I'll have to figure it out.

MR. OSTFELD: Understood, Your Honor. We'd just like to lay a foundation for Mr. Gibson's opinions in the event that

you decide this is a jury question.

THE COURT: Well, he's already persuaded me that they didn't consider it and the plaintiffs have conceded that Conti didn't consider it.

MR. OSTFELD: If --

THE COURT: The question is whether she should have.

MR. OSTFELD: If you're persuaded, Your Honor --

THE COURT: And whether or not her opinion is reliable. She has tended to opine on things with a very broad brush. And this is one of them.

MR. OSTFELD: If Your Honor is persuaded as to the soundness of Mr. Gibson's reliability on this methodology, I will --

THE COURT: You can move on.

MR. OSTFELD: I can conclude my questioning on this point.

BY MR. OSTFELD:

Q. So, all right. Then, Mr. Gibson, let's just move into the final slide where I just want to tie this back to Professor Conti's damages calculations.

You've said that there are two class-wide damages calculations. I just want the Court to understand which of your three opinions apply to which of those calculations.

So to begin, can you again remind the Court what Professor Conti's two class-wide damages calculations are?

A. Professor Conti's first class-wide damages calculation uses IQVIA data for volume and IQVIA data for pricing, and that resulted in approximately $1.3 billion in damages.

Professor Conti's second calculation uses IQVIA volume and then substitutes that with pharmacy claims pricing, and there she calculated approximately 300 million, $319 million in damages.

Q. All right. If Professor Conti presents her first damages calculation at trial using the IQVIA pricing and the IQVIA quantity data, which of your three opinions apply in rebuttal to that calculation?

A. All three opinions would apply.

Q. And if Professor Conti only presents her second damages calculation at trial using the pharmaceutical claims data and the IQVIA quantity data, which of your opinions would apply in rebuttal to that calculation?

A. Opinion 2 and Opinion 3 would apply.

Q. All right. Thank you, Mr. Gibson.

THE COURT: Okay.

MR. OSTFELD: I'll pass the witness, Your Honor.

THE COURT: All right. Let's take a five-minute break and we'll come back for cross.

THE COURTROOM DEPUTY: All rise.

(Recess was taken at 2:31 p.m. until 2:36 p.m.)

THE COURTROOM DEPUTY: All rise.

THE COURT: Okay. Cross.

CROSS-EXAMINATION

BY MR. DAVIS:

Q. Hi, Mr. Gibson. Nice to meet you in person. We did two video depositions.

A. Good to meet you as well, Mr. Davis.

Q. So let me just narrow what I'm going to ask you about today, because I just want to start with, you're not in any way offering an opinion on Dr. Conti's full refund methodology; is that correct?

A. I'm not offering beyond her full refund methodology, no.

Q. And you're not challenging her actual calculations. In fact, I think you said on direct that you were able to replicate them, right?

A. I'm not challenging the mechanics of that calculation in terms of she got to 1.3 billion and 300 million, no.

Q. In fact, I think you said you were actually able to replicate her numbers, correct?

A. I was, yes.

Q. And I think Mr. Ostfeld started by saying that you were withdrawing your opinions regarding DIR; is that correct?

A. That's correct, yes.

Q. So you won't be arguing to the jury that any damages calculations should be reduced by any rebate activity, correct?

A. Correct, no DIR-related information.

Q. And the same thing would be for the risk corridor or risk sharing subsidy, correct? You're not going to be arguing that that CMS subsidy should reduce any damages amounts in the trial, correct?

A. I won't be arguing the risk corridor would be reduced.

Q. Okay. So let's start with your critique of the IQVIA data.

I would say that your critique sort of falls into two buckets, right? One being you look at some IQVIA documents. I think Mr. Ostfeld went over them, the data disclosure policies, the email that I believe was referenced, and then you compare it to what you call benchmarks, correct? Those are sort of your two looks at IQVIA, right?

A. My methodology relies on the benchmarks. The IQVIA documentation to me is not part of my methodology. It was corroborating. So, you know, I think, as I testified, I looked at the benchmarking information and looked to see if IQVIA was consistent with those benchmarks. That's my methodology. The IQVIA documentation corroborated that, and then it kind of gave some, I'll say, alignment with that, but that's not what I used to form my opinion.

Q. So you're not independently relying on any of the IQVIA statements, are you?

A. It's corroborating to my analysis.

Q. Okay. In fact, the email, which I have a copy of --

MR. DAVIS: May I approach, Your Honor?

(Handing out documents.)

THE WITNESS: Thank you.

BY MR. DAVIS:

Q. Which portion of the email did you find -- did you use in your work? Because this document is listed in your reliance materials.

(Court reporter clarification.)

MR. DAVIS: Sorry. Let me strike that and rephrase.

BY MR. DAVIS:

Q. Which portion of this email, which is listed in your reliance materials, are you using for your opinions?

A. So the focal -- so just to state it there, this email corroborated my opinion. So, again, my methodology was the benchmarking. What I pointed out that corroborated it was that special considerations component, for example, that says: "Please note, a notable portion of pharmacies report list price in this field rather than the amount collected, therefore, the field should be used with that caveat in mind." That aligned with what my findings were.

Q. And I think I asked you at your deposition, did you ever talk with anyone at IQVIA to understand what they meant by this?

A. I didn't speak directly with anyone at IQVIA, no.

Q. That was true at your deposition, and it's true sitting

here today, right?
A. Yes, that's correct.
Q. In fact, I think you told me at your deposition that you didn't have an understanding of what was meant by notable when it says, "Please note, a notable portion of pharmacies will report list price."
You didn't understand -- do you have any understanding of what "notable" means, sitting here today?
A. They don't define what "notable" is, so...
Q. And you didn't investigate what notable meant by, for example, talking to anyone at IQVIA, correct?
A. No. I haven't spoken directly with anyone at IQVIA.
Q. And how about "list price," did you -- I think you told me at your deposition that you didn't understand what they could have meant by "list price" here.
Have you since done any -- I think you testified that you haven't talked to anyone at IQVIA. That's still true, you don't know what they mean by "list price," correct?
A. I don't know specifically what they mean by "list price," but I think -- because I also mentioned in my deposition, list price is generally thought to be higher than the negotiated price. So that's the point that I take from this; that it's a higher price that's being reported instead of the actual negotiated price, which aligned with the findings I was seeing when I performed my benchmark analysis.

Q. There are a number of ways to define -- potentially define list price, right? You just didn't investigate what was meant here, right?

A. I didn't investigate what they meant specifically here. Again, it was corroborating for me. You know, I saw a distinct difference and a significant difference between the IQVIA data and the benchmarks. And this comment indicated that there's going to be instances where a notable portion of pharmacies are reporting something higher than the negotiated price. So it was not something that was necessary for me to do.

Q. But you can't identify a single instance where a drug was not sold at list price and inaccurately reported to IQVIA as a list price? You can't identify a single instance where that actually happened, right?

A. I can't do that because IQVIA doesn't provide transactional-level detail, which is part of the reason why I wanted to use those other benchmarking datasets that do actually provide the transactions and I can see the negotiated price.

THE COURT: And why you shouldn't rely on IQVIA?

THE WITNESS: And why I shouldn't rely on IQVIA, because you can't see it.

BY MR. DAVIS:

Q. Did you investigate as part of your assignment as to how often pharmacies, in particular small pharmacies, do in fact

sell at list price?
A. I haven't investigated that, no.
Q. You were shown several -- I think you were shown an IQVIA data disclosure policy and use in litigation proceedings documents from IQVIA, correct?
A. Yes.
Q. Okay. But those are nowhere in your actual reliance list for your two reports, are they?
A. As I mentioned before, those were corroborating documents for me. So, no, they're not in my reliance list, but I used -- my methodology focused on the benchmarking. These were corroborating documents.
Q. So at the time you actually wrote your report and supplemental report, you were not relying on those documents because they weren't in your reliance list, correct?
A. That's correct.
Q. I think you mentioned at your deposition -- last deposition with me that you thought it -- you agreed with me that it's important to consider the context in which several of those statements that Mr. Ostfeld pointed out appeared, right, and to consider them in the context of the whole document, right?
A. I believe I said any excerpt should be considered in the context of the whole document, yes.
THE COURT: Are you still -- are you still talking

about the statement in Exhibit 9? Is that what you're referring to?

MR. DAVIS: Oh, no. No, Your Honor. I'm now moved on to several IQVIA sort of policy documents.

THE COURT: Statements.

MR. DAVIS: Statements, I guess, that Mr. Ostfeld I believe showed Mr. Gibson on his direct. And for the first time it is on redirect at his second deposition showed to him as well. So I wanted to address --

THE COURT: Whether he's investigated those statements?

MR. DAVIS: Well, or considered other statements that IQVIA makes in those documents.

BY MR. DAVIS:

Q. For example, IQVIA states that its data is highly reliable, including for academic research purposes, right? Are you aware of that statement in one of those documents?

A. Yeah. I believe I even mentioned here that for marketing and sales and then academic research were some of the reasons they listed in both that document and the data source document. Within the four corners of the data was my testimony before.

THE COURT: Are you aware of any other case where damages were calculated based solely on IQVIA data?

THE WITNESS: I'm not aware of another case where IQVIA was used for damages, no.

THE COURT: Have you been involved in other cases with damages claims such as the kind here?

THE WITNESS: I would say I've been involved in other damages matter focused on pharmacy pricing information. And in those cases IQVIA has not been used as a source for pharmacy prices.

BY MR. DAVIS:

Q. Are you aware that -- well, let me ask you a follow-up question to that. Did you investigate at all how often IQVIA has been used to model damages in litigation?

A. I haven't looked at how often IQVIA has been used in other cases, no.

Q. So you wouldn't be aware, for example, that Dr. Stiroh testified at her deposition that she used IQVIA pricing data in litigation for damages?

A. I believe she also put some qualifications around that, which I would as well. I mean, I'm not saying IQVIA data is no good for any use, as you asked me. I'm saying that in this case, according to the specific analyses that I performed, the pricing information for IQVIA did not align. It was higher. And the documents we've been discussing corroborate that. But my analysis was still the difference of pricing.

Q. And we'll get to your benchmarks. But I guess my question is, which you've answered, which is you didn't investigate how often IQVIA is used to actually model damages in litigation,

right, including by experts on both sides of this case?
A. I have not researched that, no.
Q. Okay. And you're not holding yourself out as an expert on how -- whether using IQVIA for litigation purposes generally?
A. No. It's specific to this matter and my findings specific to the IQVIA pricing.
Q. Did you review any testimony from the fact witnesses, the manufacturers' own employees, as to how they use IQVIA and whether they use it and for what purposes?
A. I believe I read some of that before, yes.
Q. Can you point me to where in your reliance materials you would have listed that?
A. I -- you said IQVIA fact witnesses? I thought you said the manufacturer employees. Sorry.
Q. No, no. Let me restate the question.

The manufacturers themselves, the manufacturer defendants and their employees, did you review anything from them about how they used IQVIA data and for what purposes and what they think about it?
A. I can't remember specifics, no.
Q. It's not in your reliance materials, is it?
A. No. I cannot remember any, no.
Q. Well, do you want me to show you your reliance materials?
A. I can't remember any specifics I've read of someone from the manufacturers testifying how they -- or testifying about

how they use the materials, IQVIA.

Q. Are you aware that Dr. Conti's damages analysis in the *Blue Cross Blue Shield* case involving adulterated drugs used IQVIA pricing data?

MR. OSTFELD: Your Honor, I have to object to this. And Mr. Gibson has already testified he doesn't have the foundation to testify about use of IQVIA in other cases. He's also not a lawyer.

THE COURT: Yeah. That's what he said. Yeah.

Did she say that? Refresh my recollection. Did Conti say that?

MR. DAVIS: Say what, Your Honor? Sorry.

THE COURT: That that analysis -- that IQVIA was used in the *Blue Cross*?

MR. DAVIS: It was, Your Honor.

BY MR. DAVIS:

Q. So back to the manufacturer witnesses, do you want me to show you your reliance list or will you take my word for it that you didn't list any manufacturer witnesses on your reliance list for your two reports?

A. That's -- yeah, I'll take your word for that, yes. Thank you.

Q. Okay. So, for example, you wouldn't have been aware -- I think you used the term "benchmark" quite a bit in your direct. Are you aware that ZHP's Hai Wang testified that IQVIA pricing

was a benchmark, quote, benchmark in his words?

MR. OSTFELD: Objection. Objection; foundation and context.

THE COURT: Yeah. I certainly don't know the context the question was asked.

MR. DAVIS: I can make a proffer.

THE COURT: Just yes or no, do you know about that statement?

THE WITNESS: I don't know about that statement, no.

THE COURT: Okay.

BY MR. DAVIS:

Q. You didn't consider it in your evaluation of whether Dr. Conti's --

THE COURT: He did not because he didn't know about it.

MR. DAVIS: Okay.

BY MR. DAVIS:

Q. Are you aware that Teva uses IQVIA pricing data to prepare and submit its SEC filings, including the 10-Ks and 10-Qs?

MR. OSTFELD: Objection; foundation.

THE COURT: Is this an apples-to-apples kind of a thing?

MR. DAVIS: It's showing how these -- Your Honor, it's showing how these manufacturer defendants believe in IQVIA's pricing data. They paid millions of dollars per year

for subscriptions to it. They call it a benchmark. Teva uses the pricing data, for example, in preparing its SEC filings, which obviously have to be accurate as a matter of law.

They rely on that, that pricing data in coming up with, you know, in preparing those publicly filed 10Ks and 10Qs that report sales. And he didn't.

BY MR. DAVIS:

Q. And my question of Mr. Gibson is that in doing your -- in your methodology of considering Dr. Conti's use of IQVIA, you didn't evaluate any of that, any of the manufacturers' own statements, uses, and beliefs regarding the accuracy of IQVIA data, did you?

A. I didn't evaluate statements for how the manufacturers were using it. I would say that I'm not certain in that context specifically how they're using it. So one of the points that I testified about was it is widely used and they provide caveats on price. So I -- I would -- I don't know how they're using it, and they could be using it within the context of what IQVIA recommends.

Q. You could have asked them, though, they're the ones who hired --

THE COURT: I think we're getting a little far afield. It's an apples-to-apples, and basically what you're trying to argue with this witness is that they used IQVIA when they want to, and when they don't, they don't. And that

becomes argumentative. He's not aware of any case similarly situated where this IQVIA data has been used. And I think it ends there.

MR. DAVIS: Okay.

BY MR. DAVIS:

Q. You agreed with me, Mr. Gibson, at your deposition that there is pretty substantial pricing variability for prescription drugs in the U.S.; is that right?

A. I believe I said there's variability in pricing for prescription drugs, yes.

Q. And that variability includes by pharmacy type, correct?

A. There can be variability by pharmacy type as well, yes.

Q. Correct.

And by pharmacy type, I mean large chain, big box grocery store-based pharmacies versus small independent pharmacies, right? There is pricing variability based on pharmacy type in that sense, correct?

A. There's generally pricing variability, yes.

Q. Okay. And I believe you testified that you don't have any analyses in your report that quantify that variability by pharmacy type, correct?

A. I didn't quantify variability by pharmacy type. But I would also state that that's not a goal of my analysis of the -- the --

Q. Sorry. Go ahead.

A. Sorry. What I was looking at was the prices across those types and its average prices, and that's how I was doing the benchmarking in those comparisons.

Q. You didn't -- it's just that you didn't consider the pricing variability by pharmacy type at all in your analyses, correct?

A. I didn't perform any analyses to quantify it.

Q. Okay.

A. It's inherent in the analysis I'm performing, that variability, those price points in each of the datasets are present.

Q. Well, I'm not sure I agree with that, though. If you look at the nine -- let's take the pharmacy defendant data, for example, that comes from the nine largest -- large chain, big box, grocery store and large mail-order pharmacies in the country, correct?

A. That's correct, yes.

Q. It doesn't include any data from small independent pharmacies, does it?

A. That's correct.

Q. Okay.

A. But that -- why I say it's included in the dataset, so my analysis wasn't looking at that in isolation, it was looking at that data in comparison to things like the MSP claims data and the PDE data and the Part D data, which are broadly inclusive.

The Part D data, for example, includes all transactions across the program.

Q. Well --

A. And from all of those channels, and the pricing was consistent overall.

Q. We'll get to those. I'm focused on the pharmacy defendant data benchmark right now.

And that's from nine pharmacies, correct?

A. That's correct.

Q. Nine, all of them the largest, large chain, big box, grocery store-based, large mail-order pharmacies in the country, correct?

A. They're nine large pharmacies that account for 70 percent of the overall market. So they're big, but they're also most of the market.

Q. How many pharmacies are there in the U.S.?

A. I don't know off the top of my head.

Q. 50,000?

A. About that.

Q. 70,000?

A. Yeah.

Q. Okay. And would you agree with me that IQVIA pulls from a much broader range of pharmacies than these nine -- nine exclusively large pharmacies in the pharmacy defendant data?

A. Well, I don't know the specific number of pharmacies.

IQVIA samples from a, you know, broad array of pharmacies, but I don't know the exact number. They don't publish that.

Q. You didn't analyze how that -- how pricing variability by pharmacy type might have skewed the pharmacy defendant data lower for pricing than the IQVIA reported data which pulls also from tens of thousands of small independent pharmacies, correct?

A. I did not. But I disagree; part of the reason I do that is I disagree that it skews it. As I mentioned, the pharmacy data was consistent with the other datasets I saw. And I think that also, as I testified earlier, relies upon an assumption that the IQVIA weighting of the pharmacy types is an absolute fact, which is, you know, not something the way in which I would use the IQVIA data or the way in which I think IQVIA was instructed for data to have been used.

Q. Well, let's dive into that.

But you haven't done that analysis, have you?

A. Could you ask your question again? I'm sorry. Specifically what analysis?

Q. You haven't actually done any analysis to understand or quantify how pricing variability between large -- the largest pharmacies in the U.S. and small independent pharmacies could have affected the price as reported in the pharmacy defendant data versus the price as reported in the IQVIA data which does include tens of thousands of small independent pharmacies,

correct?

A. I have not done an analysis of the variation -- of that variation, no.

THE COURT: So let me just ask this question: It seems to me that much of this questioning is going, if the Court were to allow the testimony, goes to the weight of the testimony and not to the 702 issue.

MR. DAVIS: Well, I think it -- sorry.

THE COURT: Because if I were to allow Conti to testify, this would be what the cross would look like of this witness. It seems to me that that would be going to the weight of the testimony.

MR. DAVIS: It certainly, I think, can be viewed that way, Your Honor. But I think it's also to the methodology. Mr. Gibson didn't examine pricing variability, of which there is literature out there that shows that drugs are more expensive at small independent pharmacies often by a lot.

THE COURT: So how does the Court resolve that? On the one hand, the defendants say that your witness used methodology and relied on data that she shouldn't have relied on at all. It was impermissible. And on the other hand, then the plaintiffs take the position that this witness didn't do a thorough enough analysis to rebut the fact that she shouldn't have used the data at all.

It kind of seems somewhat of a syllogism and we're

going around in circles. So either this Court has to decide whether her analysis relying on IQVIA data is permissible or not.

This witness would be permitted to testify that it was a flawed analysis. Number one, it shouldn't have been used. And number two, if you are going to use it, that it's a flawed analysis because of the benchmarks that he ascribed to it.

The plaintiff then turns around and says, okay, we don't agree with Mr. Gibson because he didn't look at all the variables with respect to sizes of pharmacies, et cetera, et cetera. That all sounds like a weight argument to me.

MR. SLATER: Your Honor, we default to both experts testifying.

THE COURT: What?

MR. SLATER: The plaintiffs default to both experts testifying on a weight basis if that's the choice.

THE COURT: "Default to," what does that mean?

MR. SLATER: Meaning that Your Honor questioned whether it's a weight of the evidence issue as opposed to an exclusion based on methodology. And from the plaintiffs' perspective, we believe that the appropriate place to end up is more than likely both experts will testify and the jury will determine the weight to give to their testimony.

THE COURT: Well, I think the sole question that I am

wrestling with is whether or not Conti testifies at all relying on the IQVIA data. I think that's the sole question. And from there, if I permit her to do so, this witness's testimony seems perfectly permissible.

MR. DAVIS: If it's a -- sure. And if it's a weight argument, we're happy to live with that result.

THE COURT: It's only a weighted argument if the argument comes in at all -- the opinion comes in at all.

MR. DAVIS: Well, in that case, I would encourage you to let me do my cross with Mr. Gibson.

THE COURT: Not if it's going to the weight. Let's assume in your analysis that the data comes in, any of those questions thereafter, I think the only probative cross-examination should be this witness's testimony that reliance on the IQVIA data is not reliable. That's the sine qua non of his testimony.

MR. DAVIS: And we --

THE COURT: Not whether you can nitpick at why he -- as to the analysis and why the damages are wrong but why it's impermissible to rely upon that data in the beginning.

MR. DAVIS: And that does sound, I think, like a weight argument because, you know, we obviously take issue with his benchmarks. I would go through them and point out his what we perceive as methodological shortcomings as well, which does get to 702.

But if Your Honor does determine it's a weight issue, then both experts should be permitted to testify.

THE COURT: I don't know. I have not heard testimony that this type of data has been relied upon in calculating these types of damages in these types of cases.

What I've heard is that they're unreliable; that this data is unreliable, you shouldn't use it for litigation purposes, and that's what I've heard.

MR. DAVIS: We're happy to cite cases to Your Honor where IQVIA is used to calculate damages.

THE COURT: Did Conti use them before?

MR. DAVIS: In the *Blue Cross Blue Shield* case, Your Honor.

MR. SLATER: Extensively.

THE COURT: And where was she -- no need.

Where was she excluded?

MR. DAVIS: She wasn't excluded in that case. Her opinion survived a Rule 702 challenge, and she was -- the case settled on the footsteps of trial. But, you know, she had passed a 702 challenge to her methodology and was fully prepared to go to trial and assess damages based on IQVIA data.

THE COURT: Limit your questioning solely to the reliability of the IQVIA data.

Did you want to say something?

MS. BROWN: I did, quickly, Your Honor. Just because

I did ask Dr. Conti about her reliance in the *Blue Cross Blue Shield* case on what data she used.

The only publicly available report we have shows that she used transaction data from the TPPs in that case.

THE COURT: And not the IQVIA data?

MS. BROWN: And not IQVIA. Doesn't mention the word "IQVIA" in her hundred-page report. And I asked her, ma'am, maybe you were mistaken when you said you used IQVIA, and she said something like, well, the report references transaction data, but I also considered IQVIA.

So to be clear, the report you can get off the docket that is publicly available makes no mention of IQVIA and, in fact, talks about the transaction-type data, pharmacy data, data from the TPPs like Mr. Gibson used from MSP.

THE COURT: Why are you telling me that she used the IQVIA data when she couldn't answer the question directly to counsel?

MR. DAVIS: It was a class damages report, Your Honor. IQVIA is the only available data to use. It's the best available and only available data. The PDE data from plans, Part D plans, for example, those are business records. The claims data from MSP, those are business records. That data is not available. The PDE data submitted to Medicare is not available. Mr. Gibson relied on a one-page summary file for comparing IQVIA to the Medicare Part D data.

The IQVIA data is the best available and only available data for the class, for the class side of calculating damages. And I think that's -- you know, and I'm happy to go back and double-check myself here, but Dr. Conti's class damages calculations in *BCBS* were using IQVIA data.

THE COURT: Okay. You'll let me know, but finish up with this witness.

MR. DAVIS: Okay.

BY MR. DAVIS:

Q. You don't take issue with IQVIA's reported quantities in your opinions, do you, Mr. Gibson?

A. My opinions don't take issue with the quantity, no.

Q. Okay. So I want to talk about this slide.

(Counsel conferring.)

MR. OSTFELD: It is slide 40.

MR. DAVIS: Slide 40. Okay. Thank you.

Got it. Okay.

BY MR. DAVIS:

Q. You recall this slide of your presentation, correct?

A. Yes.

Q. Okay. And that was to rebut Dr. Conti's opinion that as the pharmacy defendant data approximates IQVIA in terms of quantities, that you see a convergence I believe was the word you used in direct on the prices, right? And you're rebutting that conclusion including with this slide, correct?

A. I was demonstrating that if you disaggregate the analysis that Dr. Conti performed, that that convergence doesn't hold.

Q. Okay. Well, let's look at those numbers.

MR. DAVIS: May I approach, Your Honor?

THE COURT: Yes.

THE WITNESS: Thank you.

BY MR. DAVIS:

Q. Do you recognize this as Dr. Conti's supplemental damages expert report that was dated I believe in December of 2023?

A. Yes.

Q. Okay. And I'm going to focus on a series of tables that started at page 4, Tables 1, 2, 3, 4, 5, 6 and 7. It's pages 4 to 8.

Do you see those?

A. Yes.

Q. Okay. Do you dispute any of the numbers in those tables?

A. I don't dispute the numbers as they appear. So I don't dispute that Professor Conti performed an analysis that showed IQVIA is, for example, projecting quantities of 24 million for the valsartan, 160-milligram, or the quantities that were recorded in the pharmacy dataset.

So I don't -- the numbers that's shown that way I don't dispute. I dispute how she's using the comparison, just to be clear, but I don't dispute the numbers. That she calculated those numbers, let me put it that way.

Q. And I think you just told me you don't dispute the IQVIA or the pharmacy dataset quantities, correct? That's not something you dispute?

A. I don't have an opinion disputing the quantities. But I've also testified that those quantities are based upon a sample extrapolation, and so I dispute how they're being used in some of these instances. So I did testify that I disagree with using those quantities to compare them, you know, use them as a fact and compare them to another dataset and validate it. And that's -- so the use of them, not the numbers or that they calculated.

Q. Let me just read to you from your second deposition. "You don't have any reason to doubt the accuracy of IQVIA's volumes, do you?"

"Answer: I have not done any independent study of IQVIA's volumes or extrapolation methodology."

Is that still your testimony?

A. That is, and consistent with what I just said. I don't dispute how they extrapolate it. I dispute with how they're being used.

Q. Okay. So let's take the -- let's start with Teva, which is the green plotted chart on page 40 of your PowerPoint. Is there a reason the X axis only goes to 60 percent there?

A. Is it a reason?

Q. Yeah. As opposed to the other two which go 100 percent.

A. I think that's where the observation stopped.
Q. Right. And, in fact, for Teva the pharmacy defendant data only captures 39 percent of the quantities that IQVIA captures, correct?
A. I think -- the IQVIA samples pharmacy -- so, I'm trying to explain this myself here. Sorry.

The IQVIA, I agree that if you take as an assumption that IQVIA's projected totals are the totals for the whole market, that is the percentage you get.

What I objected to was assuming that that is an absolute number, that that's -- and also the -- and that that's absolutely correct. So there's, you know, it is a sample with an estimate.
Q. But you're not disputing it, at the end of the day? It's kind of we're mincing words here, but you're not disputing the quantities, right?
A. I'm not disputing it for how she uses them in her calculation.
Q. Okay.
A. So that's where -- I mean, my opinion was focused on her damages calculation. So I'm not disputing how she uses those numbers in her calculation as an estimate of the volume.
Q. Okay. And for Teva, that's only 39 percent of what IQVIA captures, right?
A. In the pharmacy claims data related to Teva, it's -- the

volumes there are 39 percent of what IQVIA estimates.
Q. Okay. And, in fact, if you look at Table 4, almost 90 percent of those Teva volumes in the pharmacy defendant dataset are mail order, right?
A. For Teva valsartan, 160-milligram.
Q. Sure. And it's 68 for 320. 97 percent for 40-milligram?
THE COURT: Can you just tell me the point you're trying to make because I am lost.
MR. DAVIS: Sure.
BY MR. DAVIS:
Q. Would you agree, Mr. Gibson, that mail order, there's substantial evidence out there that mail order is cheaper?
A. Mail order can be cheaper than retail. That's correct.
Q. In fact, the Department of Health and Human Services has said that, right? They've said that mail order is routinely a cheaper way to fill prescriptions than going to the pharmacy counter, right?
A. Mail order can be cheaper than going to the pharmacy counter, that's correct.
Q. And the Teva data here is, by a huge preponderance, overrepresented by mail order, right?
A. Well, again, that's where I have not agreed, is that the weighting -- so this is back to we talked about using the IQVIA data in the four corners, so using the specific weightings that's showing up in IQVIA to invalidate the other weightings

is where I disagree. Because when I look at the Teva prices for valsartan in the pharmacy data, they're consistent with the other benchmarks that I see.

So that's -- you know, so I don't agree that for these products the pricing appears to be impacted by a weighting in the pharmacy data.

Q. You, in fact, I think testified that you did not attempt to consider how mail order prices might affect your analysis, right?

THE COURT: Okay. I'm going to just cut this, curtail this. This is really going to the weight of the evidence. Let's focus on whether or not IQVIA is a reliable source or not. You'll persuade me, yes or no, that Conti used such data in the *Blue Cross Blue Shield* case and whether experts have used it in the other field. This expert is not aware of it being used in any other similar case. It itself says it's not to be used as a reliable factor, so you'll have to persuade me.

But all these questions are going to his analysis and that goes to the weight. It's jumping over, if you will, leapfrogging over the issue of whether or not it's even a reliable source to begin with under 702. So focus on that or I'm going to cut you off, no more questions.

MR. DAVIS: Okay. Well, let me -- I'll just make a short proffer then and I'll move on.

THE COURT: Okay.

MR. DAVIS: Which is that Torrent -- like if you actually look at the quantity, you know, 100 million Teva quantities are omitted from the pharmacy defendant data that IQVIA reports on. Those 100 million quantities were overwhelmingly filled at small independent pharmacies because this retailer data only is the nine largest pharmacies. There is pricing variability that Mr. Gibson acknowledged.

THE COURT: Okay. But the question to ask, I'll ask the question, is how can you say that the IQVIA data is unreliable when it, in fact, considers other sources that your analysis hasn't considered?

THE WITNESS: Because when I compare the IQVIA data to benchmarks that, again, I'll take the Part D information that's, again, 58 or 56 percent of Professor Conti's damages. The Part D data includes all sources, retail, mail order, everything, it's everything for Part D. Those prices are consistent with what I saw in the pharmacy claims data and I saw in the MSP claims data, which is a census for those two third-party payors.

So, you know, I disagree with the statement that the pharmacy data has a weighting that is skewing the pricing. When I look at the pharmacy data, it's consistent with the other benchmarks. IQVIA is inconsistent with the other benchmarks in every instance, even across ZHP Solco and

Torrent.

MR. DAVIS: My issue, Your Honor, is he says they're different but doesn't examine why they might be different. It's -- and so -- and I'll give Your Honor the example of Torrent's, where 75 -- in contrast to the 39 percent of almost all mail order prescriptions that are with Teva, the pharmacy defendant data captures 75 percent of the quantities that IQVIA has for Torrent. And lo and behold, the pricing converges. The pharmacy defendant data shows very similar pricing for IQVIA.

THE COURT: But I think you're missing the point, is that you're not an expert, okay. The experts have testified as follows. This expert has testified, the other expert has testified that they're not aware of any other case that's used this type of data. And I don't recall Conti saying that she is aware of any other cases that have used this type of data. I don't know. I'll have to go back and see what her testimony was with respect to the *Blue Cross* case. You know, counsel mentioned that she didn't quite say what she said. I'm going to go back and take a look at that. But that to me is really what the focus of this examination should be and not whether or not we can nitpick at how, you know, each side has come up with their damages calculation.

It still to me is whether or not this is the type of data that's reasonably relied upon by experts in this type of

field.

And I don't recall Conti saying that she is aware of any other experts using this type of data. I have to go back. And I still haven't read her testimony, because I want to be able to read it in connection with what the damages briefing is going to show me.

But all right. Can you wrap it up?

MR. DAVIS: Sure. And I can move on. And we're happy to provide you cases where it has been used as well.

And just I'll -- I understand you want me to move quickly through this stuff, I'll address a few high points.

BY MR. DAVIS:

Q. With respect to the MSP data, that's .07 percent of the class damages, correct?

A. It's a small percentage of the class damages, but it's a hundred percent of the MSP and the EmblemHealth and SummaCare, for those third-party payors, but for them it's their census.

Q. Sure. And I think you said it was apples to apples, but there is no way to actually go look at a claim in the MSP data and find that equivalent claim in IQVIA, right?

A. Well, that's part of the problem, yeah. So, yes. And that's exactly what I'm saying, is that the IQVIA -- the MSP data, I can specifically look at each and every one of those transactions and see the negotiated price and then I can actually even tie that directly to pharmacy claims data where I

can match similar transactions and do the same to PDE data, for example. The IQVIA data is the only dataset where I can't do that. I can't match the transaction level, and it's the only dataset that's higher by about a consistent amount.

Q. Well, you can't do that with your Medicare Part D summary file either because that's not data, that's a one-page summary file, correct?

A. For SummaCare and EmblemHealth I can, and I did. So for SummaCare and EmblemHealth, they have the PDE data, which the PDE data is what is used by CMS to create that Part D dashboard. So in that instance, absolutely, those two payors, which is their census for Part D, I can match those transactions.

Q. Are payors' PDE data publicly available, to your knowledge?

A. They're not publicly available, they're available by request through ResDAC.

(Court Reporter clarification.)

THE WITNESS: It's R-E-S-D-A-C, I believe.

BY MR. DAVIS:

Q. And you're not guaranteed they're -- have you requested that data?

A. I haven't requested it, the PDE data from ResDAC, no.

Q. And you're not aware whether they would even give it over if you request it, are you?

A. There are conditions around them providing that, yes.
Q. And the only way you got the assignors' PDE data in this case is because it was produced in discovery under a protective order, correct? These are confidential business records of these companies, right?
A. I agree, that's the only way I got the PDE data for these two entities, yes, applied.
Q. Okay. Let's talk about the Medicare subsidies that remain in your report.

So I think you said you're not offering an opinion on the risk corridor subsidy anymore, right?
A. I'm not offering any opinion on the risk corridor subsidy. I would say I wasn't previously performing an analysis of the risk corridor subsidy, was reducing it, the DIR, so...
Q. Sure. But you won't be offering an opinion to the jury that the damages should be reduced by any risk corridor payments from CMS, right?
A. I will not, no.
Q. Okay. Let's talk about the direct subsidy. I think you defined it in your deposition as a payment by CMS to subsidize the plan's provision of the Part D benefit, right? Is that still -- is that accurate?
A. That's correct, yes.
Q. Okay. And that subsidy is paid prospectively based on the Part D plan's bid for the upcoming calendar year, right?

A. I don't agree that it's paid prospectively in this sense; that subsidy is estimated as to what it should be and then estimated payments are made on a monthly basis that's reconciled, as I believe was the testimony, at the end of the year. So the term "prospective" isn't the way I would frame it. You know, they're receiving payments in advance of, frankly, the reconciliation.

THE COURT: I thought this was a legal argument.

MR. DAVIS: There's a bit of a factual foundation to it. And I'll wrap it up with this question.

BY MR. DAVIS:

Q. Which is, as a general subsidy, do you agree with what you told me at the deposition that the direct subsidy amount is not specific to any medication? Do you agree with that?

A. I agree with that it's not specific to any medication. I think as I had testified in my deposition, it's specific to a condition, and a condition, for example, an example I gave was primary pulmonary hypertension, it's specific to the medications used to treat that condition.

Q. Well, I have an issue with that, too, which is primary pulmonary hypertension is not an on-label use for valsartan, is it?

A. I don't know.

MR. OSTFELD: Objection; scope.

THE WITNESS: I don't know whether -- sorry.

MR. OSTFELD: Foundation.

BY MR. DAVIS:

Q. Okay. You would agree for all of the three remaining Medicare subsidies that you discuss and still have an opinion on, that those are all applied post point of sale, correct?

A. So the -- I'm thinking of the words. The low-income subsidy and the catastrophic subsidy are paid post. So they are paid by CMS to the third-party payor post point of sale. They are -- at the point of sale specific transactions trigger them.

Q. I think in your deposition you said that they were after the point of sale adjustments, quote; is that right?

MR. OSTFELD: Your Honor, I'm sorry, if there's going to be impeachment, could I please have the page and line citations of the deposition?

THE COURT: Can we --

MR. DAVIS: Sure. Deposition two, 85, line 21 through 86, line 10.

BY MR. DAVIS:

Q. "DIR amounts as well as other after the point of sale adjustments. So DIR is one of them that I highlighted and then others as we discussed, you know, like the low-income subsidy and the catastrophic reinsurance," right?

A. Right. Those adjustments are applied after the point of sale. So, yes, that's part of my opinion is that Professor

Conti's use of the point of sale, for example, right, it does not include those adjustments.

Q. And you offer no opinion as to whether the TPPs were obligated to pay the full amount at the point of sale, right?

A. Can you ask your question again? I'm not sure I understand. Pay the full amount of?

Q. The full amount assigned to them regardless of the catastrophic or low-income subsidies. You're not offering any opinion in this litigation as to whether the TPPs paid those full amounts as determined at the point of sale regardless of whether these two subsidies may reduce those payments after the fact, including at final reconciliation, which I think you told me at your deposition was nothing is final until the final reconciliation, right?

A. Well, I agree with the last part of the statement that nothing's final till the final reconciliation. I'm sorry, I'm trying to make certain I follow your question about the third-party payors paying the full amount at the point of sale. I'm sorry. If you ask me that again to make certain I answer it correctly.

Q. Sure.

You're not offering an opinion that the TPPs are obligated to pay the full amount assigned to them at the point of sale, right?

A. Correct. So I'm not -- I am not offering an opinion that

the third-party payors pay the amount that's initially assigned to them at the point of sale, that is, adjudication; that is correct.

Q. Thank you.

You testified that you did work with the PDE data from the two assignors in this case, Emblem and SummaCare, right?

A. That's correct.

Q. And I think you were actually -- and I think you also testified on direct that that data is mandated by CMS to be maintained, collected, put together in a common format, maintained and submitted to CMS, right?

A. Correct. The third-party payors have to submit that to CMS.

Q. And so for those two subsidies that are specific, the low-income and the catastrophic reinsurance subsidies, you were actually able to go through and tabulate for those two assignors the precise number of claims that eventually had those subsidies applied to them, correct?

A. I was able to match from the PDE data to the claims data in an instance where I can match it and identify where that occurred, correct.

Q. Right. And so I think for the 9,000 -- we'll call it 10,000, 9,844, for the almost 10,000 claims you reviewed in that assignor PDE data, you found, for example, that 333 of

them had the catastrophic reinsurance adjustment in that PDE data, correct?

A. I believe that's it. I don't have the numbers in front of me. Overall it was 28 percent that have either the catastrophic or the low-income subsidy.

Q. About 3 percent had the catastrophic reinsurance subsidy that applied to the claim at some point, right?

A. I think that would be -- if that number is correct, that would be correct. I don't have the table in front of me.

Q. Okay. And for those 333 claims, I think you provided an example in your report, but for all of those 333 claims, you would be able to subtract out the amount of -- or someone would be able to subtract out the amount of that adjustment, correct, if that was mandated?

A. Correct.

Q. Okay. And you would expect that the other absent class member Part D plans would have the very same ability to do that with their PDE data, correct?

A. That's correct.

Q. And that's true also for the low-income subsidy, right?

A. That's correct, yes.

MR. DAVIS: Okay. Thank you, Your Honor. That's all I have. Thank you, Mr. Gibson.

THE COURT: Okay. You can step down. Thank you.

(Witness left the stand.)

THE COURT: If you'll gather the exhibits, please. Gather your exhibits.

MR. OSTFELD: Yes. Thank you, Your Honor.

THE COURT: Okay. Any of the parties want to be heard?

MR. SLATER: Sure.

Your Honor, briefly. Plaintiffs believe that the -- I'm going to pick it apart piece by piece. Those IQVIA documents should not be considered or admitted based on the testimony. They were not relied on. They weren't part of the methodology, and they basically amount to a legal disclaimer so if somebody uses IQVIA data and doesn't like the outcome, they can't go back to IQVIA. That's between the purchaser of the data and IQVIA, but is not a reliability issue that could be held against the plaintiffs. I think it's both under Rule 403 -- definitely a 403 issue that that should not be considered.

THE COURT: Wait. I'm losing you. So Gibson can't rely upon it but Conti can?

MR. SLATER: No. I'm talking about those IQVIA documents with the legal disclaimers in them --

THE COURT: Oh.

MR. SLATER: -- that were pulled out. We think those should not be considered at all, certainly under the Rule 403, to the extent there's any relevance. Because they're really

just legal disclaimers. And it's very clear. And they also talk about the highly probative nature of the data. Highly?

MR. DAVIS: Highly reliable.

MR. SLATER: Highly reliable.

The email we also don't believe should be relied on. It's obviously hearsay and --

THE COURT: Wait. So are you conceding that he can testify under Rule 702 and now you're making an application as to why certain documents should not be permitted before the jury? What are you asking me to rule on?

MR. SLATER: In --

THE COURT: It sounds like a concession that he's permitted under 702 with certain exceptions.

MR. SLATER: Well, what I was trying to do was undercut the basis for his opinions by pulling these pieces out and just to make clear this was not part of his methodology and that they wouldn't be considered so at least we understood what we're arguing about so we don't even have to address the email if Your Honor agrees that it would not be considered. Because, for example, he never corroborated it. It's a hearsay document. He didn't rely on it. He said he didn't have any idea what a notable percentage meant. That could have been five people. It could have been --

THE COURT: Well, I'll reserve on that, whether or not that goes before them. But an expert is entitled to rely

on any piece of evidence. And so he relied on that to inform his opinion that IQVIA data is not reliable.

MR. SLATER: I think his testimony was he didn't rely on it but he said it was corroborative.

THE COURT: Yeah.

MR. SLATER: And because it's a hearsay document and it is not reliable, for him to say that he's going to rely on it, because it will introduce significant questions, what does notable mean? He doesn't know what list price means. He didn't track it down, so --

THE COURT: Well, yeah, okay. We can argue about that document at some other point.

MR. SLATER: That's my concern. Fair enough.

I think that, to boil it up, I think that if Dr. Conti is going to testify, I think that he can testify. We've given you our argument on collateral source. We're happy to talk about it more when Your Honor feels it's the appropriate time.

As far as the IQVIA data reliability which was the big core of his testimony, I think that it's a question of weight for the jury whether the IQVIA data is reliable or not. Dr. Conti did --

THE COURT: That's a 702 inquiry. 702, has to be based on reliable -- a product of reliable principles and methods. So it is a question for this Court to determine at

the inception whether or not Conti's reliance on the IQVIA data is reliable and an acceptable practice and method.

MR. SLATER: And I think that he made some -- please, John.

MR. DAVIS: Go ahead.

MR. SLATER: -- I think he made some important concessions today that should allow the testimony to be heard on IQVIA by Dr. Conti.

Number one, he admitted it's highly reliable for academic research, which is obviously an important part of 702 and how experts are allowed to use data. If it's used in the academic world, that's an important touchstone to allow it to be used in the courtroom. And Dr. Conti testified --

THE COURT: Who connected that dot?

MR. SLATER: Dr. Conti did. She testified --

THE COURT: She connected the academic research dot to the litigation dot?

MR. SLATER: She did. She testified that she uses that regularly in her academic research, regularly relies on in her peer-reviewed literature, and I think that really gets us there enough. That's number one.

Number two, there was a brief part of the cross which I think I don't want to get lost on the Court. The manufacturers, the pharmaceutical manufacturers do see this as the gold standard data. They rely on not just for market share

but they testified for pricing data. So he didn't consider that at all. I think that's a significant methodological issue. I think it will certainly go to the weight.

But it shows that when Your Honor's questioning, well, am I going to let a jury hear this, if the actual industry based on their own admissions from their 30(b)(6) witnesses is that we use this, it's highly important to us, highly significant, and we rely on it for pricing as well as market share and other things, that's a significant thing that the Court should consider. And this witness had nothing to say about that because he didn't even know about the deposition testimony and couldn't factor that into his testimony where he said he rejects the usefulness of it, but he didn't take that into account at all. And I think that's a very important concession that the defendants have to -- have to -- that the defendants really can't get past with his testimony because he doesn't talk to it at all.

The last part was when Your Honor looks at what he said about the data, whether it's accurate or not, I'm going to use the Torrent example. Dr. Conti explicitly testified that she took the retailer data, which was on -- we understand now what that sample was, and why she says it skews towards lower prices, and she said when you have more data, and Torrent had the most, the prices become much closer to the IQVIA data, which backs her opinion, that shows, and she used that as a

corroborative fact to the reliability of the IQVIA data, that it backs her opinion, and she actually used the numbers to prove it, that when you have more claims you see that the IQVIA data becomes more and more close to the retailer data. And that's an important corroborative fact.

The defense can cross her on that. They can ask the questions that they've said they want to ask, but those factors together she's corroborated it mathematically based on data that's going to be before this jury. She uses it in academic research. The manufacturers rely on the pricing data in their everyday business and they say it's critically important to them.

On all those bases, we ask that Your Honor allow the use of that data, and we believe that Mr. Gibson can then speak to it, and the jury can decide the weight of his opinions. And then at the end of the case, if we do prevail, Your Honor has the ability, as was done in the *HIV* litigation, to look at a molding process post verdict. But we don't put that in front of the jury. Your Honor can mold to the extent the defense can actually in a reliable way match up apples to apples and give you a reliable way to apply those setoffs.

Thank you.

THE COURT: So I'll just shortcut this.

My ruling with respect to Gibson really rises or falls on whether or not I exclude Conti. And so I continue to

look at it. I continue to ask questions, which have been apparent to the parties today. And I'm not prepared to rule on Conti today.

But I found it to be -- if I were to permit her to testify, I found this expert today to qualify under 702. I saw nothing that would indicate to me, under 702(a), (b), (c) or (d), that he does not meet all of those elements. So I would not intend to exclude Gibson.

Okay. The other question that's been raised is, you folks are working on briefing, which is, you know, the source of my consternation. There was a letter on the docket either last night -- or I don't remember, but asking when those briefs should be in. And my answer is, as soon as you can get them to me, because I may have follow-up. But are the parties prepared to submit them?

MR. SLATER: Plaintiffs are prepared to submit it. You wanted simultaneous. Plaintiffs were ready yesterday. They're ready today. We're ready as --

THE COURT: So just because I can't help myself, give me a three-minute primer.

MR. SLATER: The brief will lay out the warranties and explain what the warranties are in this case.

THE COURT: Okay.

MR. SLATER: The primary warranty being the representation that the product being sold was valsartan that

was USP compliant and met the FDA approval.

THE COURT: Okay.

MR. SLATER: We provided law to Your Honor showing that -- provided law with regard to the fact that the place that you look at whether the warranty is met or breached is at the time of the transaction. And we gave you a -- we have a long list of cases where full-refund damages have been calculated from day one, despite the fact in many of those cases that the product that was sold actually provided usefulness -- I'm using the word "usefulness" broadly -- to the purchasers, and the Court still allowed full-refund damages in those cases.

We also dealt with the replacement --

THE COURT: Particular jurisdictions or across-the-board jurisdictions relevant here?

MR. SLATER: It's a pretty wide sampling of jurisdictions. I mean, it goes I believe we have -- I think there's about 15 cases. I just don't have them in front of you. I know --

THE COURT: But it would be important for the jurisdiction.

MR. SLATER: Yes.

THE COURT: Because what my initial research showed is that there are some jurisdictions that may or may not have a full refund and there are jurisdictions that have a

benefit-of-the-bargain, and it would be relevant to know which jurisdictions those are because maybe we try -- maybe we cut the case and try two cases. One's the full-refund jurisdictions and one's the benefit-of-the-bargain jurisdictions.

MR. SLATER: Judge --

THE COURT: Because it seems to me that the evidence that comes in matters.

MR. SLATER: When I said "full refund," I was talking about a full refund under the benefit-of-the-bargain. If I misspoke, I didn't want to mislead the Court.

THE COURT: But how -- well, full refund under the benefit-of-the-bargain.

MR. SLATER: Right. That if there's no benefit -- basically the construct of our case is that the products could not be sold and had no value based on all the arguments Your Honor's heard.

If the jury accepts that, they can say refund all the money as the damages. Pay all the damages for all that was paid.

If the jury agrees with the defense, well, there was efficacy so we're going to say there was some value, Dr. Conti can say, look, these calculations were prepared. And that's the other thing we've established is she assumed no value when she did her calculations. That was the assumption that

underlied her calculations. So that would not be something new to the case. And she could explain to the jury, look --

THE COURT: So now you want to switch course and say that she assumed they were zero?

MR. SLATER: No, I don't want to switch course. What she said is two things.

THE COURT: Yeah.

MR. SLATER: She said on her analysis based on economic principles she doesn't believe there was value.

THE COURT: Okay.

MR. SLATER: She relies on the finding of adulteration, she relies on that, and she says based on the facts her opinion and based on her understanding of economic principles and pharmaceutical regulatory law, there was no value. That's an opinion.

She also does the calculations which are premised on the assumption of no value. She did both.

THE COURT: It's the assumption that is not as troublesome. It's, though, the reason I'm troubled by her testimony is that her opinion does not fit the facts of this case. It's a fit problem. She wants to testify the drugs that are adulterated have no value, okay. But that's not the facts of our case. And that is where I continue to struggle.

But go ahead. So now you say she's going to assume. Okay.

MR. SLATER: I think -- I think that to jump -- because that's something else we are going to address in our brief, which hopefully, Your Honor, we can file them today or by the end of the day.

THE COURT: Get them to me as soon as you can. I'll look at them. I'm sure I'll have questions. I know you all know I will have questions.

It's just -- it's --

MR. SLATER: What --

THE COURT: I mean, I don't know how else to say this other than I don't think that these issues have been fleshed out heretofore, and they have to be fleshed out.

And what I continue to, you know, in my spare time think about is how in the world do I instruct a jury that, you know, in Arkansas it's a full-refund theory and in Georgia it's a benefit-of-the-bargain? That's my one question.

And then my second question is, benefit-of-the-bargain, if the defendants are permitted to introduce evidence that there was a benefit to these adulterated drugs, how do they do that without the causation prong?

MR. SLATER: Well --

THE COURT: That's what worries me. Because the minute the plaintiff stands up and intuits to the jury that these are cancer-causing drugs and they have a zero value, I

have now deprived the defendants of a fair trial, because they should be permitted to introduce evidence that they aren't cancer causing. That's where I -- I struggle.

I understand that when I was assigned this case, the defendants vociferously argued that I would be creating error if I continued this trial because the issue of causation. And it does continue to gnaw at me, because I think that they are raising legitimate points.

I'm not saying they are prevailing. But it's a lot to put my head around in terms of how do I -- how do the parties present this case to the jury?

MR. SLATER: I think that Your Honor, again, going back to July, you were correct that the standard, and, again, I've referred to it as a materiality issue, and you're talking about, well, is the causation what we need, that's not the standard that's applicable to these cases. The standard is a high standard. It had to be an unacceptable risk from a regulatory standpoint such that the recall was required. And that's what we have to establish. It's not that there was a smudge on the label and that was adulterated for that reason.

If we had a case like that, this would be a very hard argument for us, I think, or a much harder argument. But this was a material issue where the NDMA was recognized going back many, many years before. And the regulatory guidances that the defendants have admitted controlled their conduct, genotoxic

impurities that were not allowed to be in the drug. And when the recalls occurred, the FDA required that ZHP, for example, say it was an unacceptable risk.

So standard -- and it says in the same line, which Your Honor heard last week, there have been no adverse events reported. So the fact that nobody had gotten cancer was not relevant to the question of whether they could be sold. It was the unacceptable regulatory qualified risk based on the guidances.

And I think if you look at that and maybe you hear some more of the testimony tomorrow and that you're going to see in some of the --

THE COURT: Maybe. But let me just posit this, and they'll all jump up and down when I say this, but let's just assume for a moment they stipulate that these drugs were adulterated, just stipulate to it, and they were stipulated, but they just didn't know they were adulterated. How do I prevent them from putting on evidence that despite the adulteration they did what they were supposed to do?

MR. SLATER: I don't think you prevent that evidence, because I'm not going to try to argue that you're going to keep out efficacy.

THE COURT: Okay. So then how -- okay.

MR. SLATER: Because we've lost that argument.

THE COURT: Okay.

MR. SLATER: We objected, but we lost it, so I'm not going to go back to it.

THE COURT: Okay. You lost that argument before me or before Judge Kugler?

MR. SLATER: I think we definitely lost it before you, and I think we lost it in front of Judge Kugler as well.

THE COURT: Okay. Fair.

MR. SLATER: So we understand it's coming in.

THE COURT: Okay. They then stand up, then how do I prevent you, they stand up and they say: But these drugs did what they were supposed to do. How do I prevent you from saying, oh, no, no, no, they didn't, ladies and gentlemen of the jury, you want to know what they really did?

MR. SLATER: No; because we're not going to say that. We're not going to say they caused cancer to people. That will never be said. In fact, we've been cutting our designations and taking out anything that smacks of general causation.

THE COURT: Okay. Then I'll police you on it, because one of the questions --

MR. SLATER: And you should. I appreciate it.

THE COURT: One of the questions that was asked of one of the witnesses last week by the plaintiffs was something along the lines of -- because my, you know, my antennas went up, which is something along the lines of this: Oh, it's okay, it's okay for a company like Teva to allow adulterated drugs on

the market or something, you know, a little, you know, torrid.

So it's fine, and I appreciate it, Mr. Slater, that you're not going to get up and argue it, but there's a lot of things that can be argued without arguing them.

So let's just --

MR. SLATER: Of course.

THE COURT: I won't hesitate to police that.

MR. SLATER: On your last point, I don't think there's a problem with us talking about the problem with selling adulterated drugs. I thought your point was: Don't get up and say "these cause cancer." And that you're not going to hear.

THE COURT: The question that was asked is that, my recollection, I could be wrong, is that it was referred to as a carcinogen.

MS. ALLON: Yes.

MS. LOCKARD: Right.

MR. SLATER: It's a probable human carcinogen, and that's what the language in the documents are from the defendants.

THE COURT: What's a carcinogen say to a jury?

MR. SLATER: Well, that's what the unacceptable risk is. The regulatory standard that applies here is risk. It's not causation, because there was no causation necessary to require the recall at all.

And one of the things that I ask Your Honor to think about is from our construct of the law, and we think we're going to give you very persuasive law to show you, look at whether the warranty is being met when the person actually takes possession of the product at the counter. You don't buy the efficacy to the exclusion of the quality, the purity, the safety. It's all or nothing. And if you don't have it all, you're not allowed, as a matter of law, to sell that product at that counter.

And I think what's happening is, and I think the horserace that Your Honor has endorsed, and I think that we think we understand we're going to have to face is, we're going to argue what we're laying out; that you buy the drug as a whole. And what the defendants are doing is they're going actually later and saying, well, retrospectively, it had the strength, it helped you with this. Yes, it didn't have those other things, but overlook the fact that we never could have sold it because you got some benefit. And the jury will have the 100 percent damages and it will be explained if you don't find that, if you find that 50 percent of it was benefit, you know how to work with those numbers.

THE COURT: Right. And that's why I want a legal analysis on it, because it seems to me that an argument to the jury that it is 100 percent damages is an analysis that does not consider the benefit-of-the-bargain. And that's the

problem I'm having with Conti; that if Conti's testimony is in a benefit-of-a-bargain jurisdiction, where in order for the jury to determine what the value of damages is, inherent in that is an expert who will do the benefit-risk analysis. She did none of that. She simply said -- and I underscore "simply" -- said adulterated drugs can't be sold. FDA says so, zero.

And so she did no benefit-of-the-bargain analysis. And she pretended, i.e., no fit, that these drugs should never have been sold in the first place. And that's the problem I'm having.

But I do think it depends upon what the law of the jurisdictions is. Perhaps in some jurisdictions it's permissible. Perhaps in others it's not. That's what my preliminary research shows. That's why I'm anxious to see what you all have come up with, because I don't think it's that simple.

MR. SLATER: It's an interesting question, Your Honor, because what Dr. Conti was doing was applying the regulatory law and saying, look, under the law there's no value because you can't sell it.

THE COURT: Right. That's right.

MR. SLATER: And I think when Your Honor says there's no fit, and I say this extremely respectfully obviously, our concern is that what Your Honor is essentially doing is saying,

if I understand, there's no fit because Your Honor thinks, well, there was some value here. But my concern -- our concern is that would essentially be granting summary judgment to the defendants that there is value, and that's not something that --

THE COURT: But they're going to put on a case that shows that there was value.

MR. SLATER: And the jury will decide that question.

THE COURT: That's it.

MR. SLATER: Right. And we understand that.

So the issue with Dr. Conti is, it's not that she ignored the efficacy. And if that wasn't made clear, it's probably because the *Daubert* hearings here have been very terse, and it may have been --

THE COURT: No. It's because I don't think that the experts have done what they should have done. It seems to me that if the benefit-of-the-bargain is what the law requires, then there would have had, it seems to me, there would have had to have been an analysis of the benefit versus the risk.

So, yes, we looked at this. We've looked at the studies, which haven't been done yet, I presume. Maybe they have. We've looked at this in 100 patients. Ninety-nine of them had no issues. Their blood pressure was reduced, et cetera, et cetera. And in 1 percent, we are now seeing an issue. Okay, ladies and gentlemen, in my expert opinion,

here's how you benefit/risk analysis and you calculate the damages. That's what a benefit/risk/benefit-of-the-bargain analysis seemed to me.

MR. SLATER: Right. The Eleventh Circuit in the *Debernardis* case -- I think I got that right -- they allowed full-refund damages in a benefit-of-the-bargain case. And you have that case.

I think that ultimately, remember the defense experts say, well, there's value, but they never tried to value it. And they --

THE COURT: Well, how many times have I asked you all, how is a jury going to decide value? How many times have I asked that question?

MR. SLATER: I think the answer is the economic principles will be established by both experts, and we'll have our argument for why there wasn't value, and we'll probably have argument by the end of the case if the evidence is compelling from the defense if you do find value, this is how you should do this based on the principles the experts have supplied. So you're not running rudderless through the water. You actually have guidance of principles that you have to follow and this is what you should consider. And we'll make our argument that our experts focusing on the regulatory law that you couldn't sell it, which the witnesses all admit nobody would ever buy this.

THE COURT: I know. But those aren't your facts. And again, I go back to what keeps bugging me, which is if these were sugar pills, I don't think we would be quarreling about it. It's a full refund. They didn't do anything. But these are pills the defendants say had some value to it. I don't know how a jury determines that.

MR. SLATER: Well, I think they do it like they do in any complex case. They will take the facts, they'll take the economic principles and they'll decide was there value or not.

THE COURT: But --

MR. SLATER: And --

THE COURT: But the defendants stand up -- the defendants stand up and they say there was value to these drugs. It lowered blood pressure, lowered blood pressure, et cetera, et cetera, and then the big elephant in the room is, uhmm, but what were the risks? And then I send a jury out to deliberate and they're like, uhmm, but what was the risk? They mentioned "carcinogen."

MR. SLATER: Well, it's not --

THE COURT: I --

MR. SLATER: The point is, and you are not going to hear anybody say causation. All you're going to hear is the language that the FDA used and the defendants used, which is that it was an unacceptable risk. And that's what witness after witness admitted in the testimony.

I think also the jury very well could find, certainly as to ZHP, that they knew from the very beginning what they were doing and what they were selling.

THE COURT: That's a different -- that's a whole different -- that's a different can of worms.

MR. SLATER: That's the fraud claim. And that's a different issue.

THE COURT: That goes to your fraud claim.

MR. SLATER: So we're really arguing the warranty claim.

THE COURT: Yeah.

MR. SLATER: Okay. Because I think the Consumer -- the Consumer Protection Claim --

THE COURT: That's a fraud claim. That's a different --

MR. SLATER: Those are different animals with different standards. So, okay, I understand that, so I want to just make sure I wasn't missing an issue.

But I think ultimately, it really ultimately, when you put this all in, both experts can testify, and the jury will have the tools to make a determination of what the value is. And if Your Honor is right, and you have a lot more experience with trials than I will ever have, then the jury will have to grapple with it and come up with a value.

THE COURT: Right. I know. But part of my function

is to be the gatekeeper.

MR. SLATER: I understand.

THE COURT: And if I sit up here having a hard time figuring out how in the world a jury will even begin to conduct its analysis, I can promise you, they won't be able to. I can promise you. I've tried enough cases to know, as you've said.

I am sitting up here just confused as to how does a jury analyze the benefit-of-the-bargain. And I don't know without treading into this causation analysis.

MR. SLATER: I think the big problem that the Court is wrestling with is, honestly, a problem of the defendants' making where they take this position there was efficacy.

And, by the way, there will be evidence that the Court will hear, and we're not going to lay our trial out, but there may be some holes in this idea that, oh, don't worry there's efficacy, okay, and bioequivalence. There may be some holes in that.

So it's not definitely something that's going to be so easy. But the defendants came up, and they chose to take a minimalist, let's poke holes theory, we're not going to actually have any opinions of what happened. We're just going to say we don't like what you did.

THE COURT: Well --

MR. SLATER: They could have -- they could have -- if they want to inject, because they're injecting efficacy brings

value into the case. We didn't inject that issue. And they chose not to say and this is how you value that. So that's a problem of their own creation, not ours.

THE COURT: Well, I hesitate to agree with you on that simply because you all have a better handle of the voluminous record than this Court does. They may have been relying upon the prior rulings of Judge Kugler.

MR. SLATER: There was no --

THE COURT: So I hesitate to -- I hesitate to cast aspersions at this point.

MR. SLATER: Judge Kugler -- I didn't mean to interrupt. I'm sorry. Judge Kugler --

THE COURT: Let me hear from them.

MS. ALLON: Your Honor --

MR. SLATER: Judge Kugler allowed them to make this argument. And he never stopped their experts from giving valuation calculations to back up their efficacy argument.

THE COURT: But my recollection from his rulings is that he said that this trial will have no causation element in it.

MR. SLATER: That's a different issue.

THE COURT: Which is why --

MR. SLATER: The general causation, our understanding is, yes, it would not be in this case because it doesn't belong in this case because it's not the standard for whether the

drugs can be sold.

THE COURT: But isn't that a benefit-risk analysis?

MR. SLATER: No. Because --

THE COURT: Benefit-of-the-bargain analysis?

MR. SLATER: Because you would be importing a concept that doesn't fit here. This is a regulatory case based on whether the drugs could be sold or not. You didn't have to prove anybody ever got cancer. That's why they were pulled off the market when there was not one report of anybody getting cancer from them. This is principles that go back -- and you're going to see a lot of this tomorrow, all the governing regulatory guidances said these genotoxic impurities are unacceptable in these products. And that was something they always knew.

They tried to act like, well, we just figured this out in June of 2018, but that was the rule going back well before these products were developed. So the standard was never you have to prove it causes cancer. The standard is, this can't be in these drugs because that is a regulatory decision that was made by the FDA. And it's binding, and you can't -- and that's why the second the NDMA was known, they were obligated to pull them off the market. They didn't do so. But they were obligated to.

And that's why when the FDA found out, it was immediate recalls all over the country, not because someone got

cancer, but because it's not allowed as a regulatory requirement.

THE COURT: Right. But, again, I mean, we're talking in circles now. It really comes down to how do you prove your remedy. I think that's the issue that I continue to quarrel with.

Okay. Real quick.

MS. ALLON: Your Honor, very quickly. The definition of carcinogen is cancer-causing substance. The definition of genotoxic is an impurity that binds the DNA and can cause cancer. And so if Mr. Slater is going to use either of two words in front of the jury, "carcinogen" or "genotoxic," he is telling the jury that NDMA causes cancer, and the defendants have to be allowed to rebut it. He can say it's not causation, but that's what he's doing by using those words. That is the definition of those words. He cannot get around that.

And so if we say it has therapeutic value and he says, no, it doesn't because it's carcinogen or, no, it doesn't because it's a genotoxic impurity, we have to be allowed to respond and say, no, it didn't cause cancer.

THE COURT: In order to weigh the prejudice, can the parties stipulate that they were adulterated?

MS. ALLON: No. No, Your Honor.

THE COURT: You don't agree they were adulterated?

MS. LOCKARD: Your Honor, for Teva, and let me just

make this clear --

MS. ALLON: For Torrent.

THE COURT: Wait. Hold on one second.

Go ahead. Finish.

MS. ALLON: The FDA did not make a determination that Torrent's products were adulterated.

MS. LOCKARD: Or Teva's.

MS. ALLON: Or Teva, for that matter. So, no, it's not something that we can stipulate to.

THE COURT: Okay. All right. Fair enough.

MR. NIGH: Your Honor, the FDA did make a determination that Torrent's product was adulterated. We have an email where they got off the phone call with the FDA, and in the email they communicate internally: The FDA just told us our product is adulterated.

MS. ALLON: That's not what happened. The FDA told us --

THE COURT: Okay. I asked whether or not the parties would stipulate. The answer is no.

MS. LOCKARD: Your Honor, on the general causation issue, I've heard Mr. Slater's argument, and that is a fine argument in a strict liability case. That's not what we have here.

The question for the jury will be: Did these drugs have any value? Did they have any worth? We've talked about

this in circles.

As soon as he stands up and puts on the board an FDA announcement that there was an unacceptable risk because of the carcinogens from the NDMA, we are entitled to explain that and defend our case. We have --

THE COURT: And that's what's bugging me. And it's been bugging me. And I think if it's in a benefit-of-the-bargain -- and you're permitted to introduce that testimony. I think in the benefit-of-the-bargain jurisdictions, that's problematic. If it's in the full-refund, it doesn't matter what they were. This is how I see it. In the full-refund jurisdictions, it doesn't matter, he's just got to prove that they were adulterated. That's the problem I see. That's why I want briefing from you all, because to me it seems to matter what jurisdictions we're talking about.

MR. OSTFELD: Your Honor, on the subject of briefing, plaintiffs have indicated their brief is ready. Our brief is not. We had to get two witnesses ready for 702 hearings this week. If plaintiffs want to file, we can absolutely file within days, but we can't -- we don't have it today.

THE COURT: I'm not going to give you guys deadlines. Just file when you can. I would appreciate it. I mean, you know, I have nightmares about this topic. I think about it all day long. I'm going around in circles.

MR. SLATER: Can we say by the end of the week? I

mean, we prefer to file simultaneously as Your Honor ordered for obvious reasons, and we're ready to file. I know the defense realizes we have to participate in these hearings, too.

THE COURT: It would be far more helpful if you would file so they could respond to what you've filed.

MR. SLATER: Right.

THE COURT: And then you can respond to what they filed. Simultaneous briefing, I do it to try to be fair, but then you folks can't agree on anything. So it would be nice for me to -- file yours today. It's ready. You said it was ready. File it today.

MR. SLATER: We will.

THE COURT: When do you want to file? Can you file yours by Thursday?

MR. OSTFELD: If we could have until Friday, Your Honor.

THE COURT: And you'll file yours tomorrow then if you want another day to look at it.

MR. SLATER: Okay. Thank you, Your Honor.

THE COURT: File it Wednesday, file it Friday. You can file something in response on Tuesday.

MR. SLATER: I appreciate it.

THE COURT: I have to get this issue resolved, because I think that from that everything flows and how I try the case.

MR. SLATER: Will do.

THE COURT: You folks really can't agree on whether or not the FDA says that your drugs were adulterated, that's really kind of remarkable.

MR. SLATER: Well, and there is a ruling, by the way, to answer the question you asked before, I believe that there was a ruling that if the API was adulterated and you put it into a finished dose pill, the finished dose pills by statutory definition would also have been adulterated, because how could they not be? Whether the FDA said it or not, if they have adulterated API --

THE COURT: We're going around in circles. You can't get up and argue to the jury that these were adulterated because the FDA said they were adulterated and therefore there was a recall. And if the FDA says they were adulterated, you can't sell them and therefore there's zero value, if the law says that it's a benefit-of-the-bargain and they can put that there was value. You can argue that there was no value, but they have to be able to present evidence that they did have value.

MR. SLATER: We agree. We agree.

THE COURT: Yeah.

MR. SLATER: They can counter our proofs with their own case.

THE COURT: I know. But I sit up here and I say, for

the life of me, how do the plaintiffs not insinuate -- I'll use that word -- to the jury that these were cancer-causing drugs?

MR. SLATER: Judge, I would tell you that we are not.

THE COURT: That's what --

MR. SLATER: We're not going to do it. And I'll tell you what we're not going to tell the jury.

THE COURT: Yeah.

MR. SLATER: We're not going to tell the jury that in the large studies of these valsartan pills that were done, including the one that the defense -- remember they said there's this important new study back in July.

THE COURT: Yeah.

MR. SLATER: Those studies both found that there was a statistically increased risk of liver cancer from these valsartan pills. But we're not going to tell the jury that even though -- if we go down the general causation route, we're going to have weeks more of testimony. And ultimately the jury is going to see two studies that say, yeah, it does cause liver cancer.

MS. LOCKARD: Your Honor --

MR. SLATER: So where are we going with this?

MS. LOCKARD: -- I've heard this. I've heard this. But if you look, I've been spending hours and hours on deposition designations of the over 30 witnesses they have designated. They are replete with references to

carcinogenicity, to cancer, to mutagens. I'm looking at my toxicologist -- my Teva toxicologist, in-house Teva toxicologist, and they have designated pages of testimony talking about cancer.

THE COURT: I'm just going to shortcut this.

MR. SLATER: In the context of --

THE COURT: No. I'm going to be very clear here.

You all will know what you can and can't get into evidence before the jury. If a party violates it, I'll declare a mistrial and impose attorney costs.

MR. SLATER: Understood.

THE COURT: I would be very -- I'm very clear about it. I am not going to spend the next three months preparing for a trial, having a jury sit for a four-week trial, having spent an enormous amount of resources preparing for this trial only for a party to violate my orders. I'm going to be very clear about that. I will declare a mistrial, and I will impose the cost, which will be significant, upon the errant party.

MR. SLATER: It's well understood, Your Honor. And I can tell you the designations are being framed in terms of risk, as Your Honor had instructed in July. So that's how we're framing it.

THE COURT: We'll see. We'll see.

MS. LOCKARD: So we are then entitled to present our expert to talk about the degree of risk.

THE COURT: I don't know. I have to see -- I have to see the depositions. If there are any that you're concerned about, flag them.

MS. LOCKARD: I would like to submit our expert report to Your Honor from Dr. Chodosh on this point so you can see what this testimony would be.

THE COURT: I would rather not like to read a report. If you have snippets you want me to read, I'm happy to do that.

MS. LOCKARD: I'll be happy to provide a summary.

THE COURT: Okay. I'll see you all tomorrow. Okay.

MR. SLATER: Thank you, Your Honor. 1:00 tomorrow.

THE COURT: Yes, 1:00.

MS. LOCKARD: Your Honor --

THE COURT: Can we make it 1:30?

MR. SLATER: Sure.

THE COURT: 1:30.

MS. LOCKARD: If we may, just one other point. I know at the last hearing last week we talked about the potential for starting trial a week early for jury selection.

THE COURT: Yes.

MS. LOCKARD: We, the parties have tried to reach agreement to ensure we could get the case tried in the 80 hours, in the four weeks allotted. We have not been able to do that because of the estimates that are provided by plaintiffs' counsel that we --

THE COURT: I'm going to take a look at it all. You all put it together. I'm going to start cutting out. There's just no reason why this case should be more than four weeks.

If today's hearing is any indication of how that trial will go, that jury is going to be sleeping.

(Laughter.)

THE COURT: And there's just -- it's -- no. I'll start chopping your case.

MS. LOCKARD: Well, we would propose that we take the amount of time available, which we've all said was around 80 hours. We've done the math based on the days, split it. They get their 40 to use however they prefer.

THE COURT: Yeah.

MS. LOCKARD: We get our 40.

THE COURT: I think that's fair. So work it out. And if you can't work it out, I'll start excising.

Four weeks, that's it. We're going to do it.

Okay. I'll see you all tomorrow, 1:30.

MS. LOCKARD: Thank you, Your Honor.

THE COURTROOM DEPUTY: All rise.

(Proceedings concluded at 4:04 p.m.)

- -

FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE

- -

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/S/John J. Kurz, RDR-RMR-CRR-CRC September 20, 2024

Court Reporter/Transcriber